Trainee

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Supporting Agency (if Non-ICDDR, B)  Le of Study Study of absorption  Compliant of Project status:  Compliant of Project status:  Continuation with change  Continuation with	incipal Investigator <u>Sufia</u>	Isl	anı	Train	ce Investigator (if any)
Animal models.  Altimal models write NA  Altimal models and subjects  Altimal models write NA  Altimal models and sequire models are minors yes no  Altimal models write NA  Altimal models are minors of require Models and prosects Yes No  Altimal models write NA  Altimal models write NA  Altimal models are minors yes no  Altimation with change  Altimation militation at requirement of the subjects are minors) Yes anonymity of subjects Yes No  Altimation by it altimity and altimity of subjects Yes No  Altimation with change  Altimation approal and the following in stublects are minors) Yes anonymity of subjects Yes No  Altimation by it altimity Na  Altimation altimity of subjects Yes No  Altimation by it altimity Na  Altimation subjects are minors) Yes anonymity of subjects Yes No  Altimation by it altimity Na  Altimity of subjects Yes No  Altimation by it altimity Na  Altimity of subjects are minors) Yes on Will precautions be taken to protect anonymity of subjects are minors) Yes westing anonymity of subjects are minors) Yes No	1 ) 🗘 🖍			Suppo	rting Agency (if Non-LCDDR,B)
Animal models.  Altimal models write NA  Altimal models and subjects  Altimal models write NA  Altimal models and sequire models are minors yes no  Altimal models write NA  Altimal models are minors of require Models and prosects Yes No  Altimal models write NA  Altimal models write NA  Altimal models are minors yes no  Altimation with change  Altimation militation at requirement of the subjects are minors) Yes anonymity of subjects Yes No  Altimation by it altimity and altimity of subjects Yes No  Altimation with change  Altimation approal and the following in stublects are minors) Yes anonymity of subjects Yes No  Altimation by it altimity Na  Altimation altimity of subjects Yes No  Altimation by it altimity Na  Altimation subjects are minors) Yes anonymity of subjects Yes No  Altimation by it altimity Na  Altimity of subjects Yes No  Altimation by it altimity Na  Altimity of subjects are minors) Yes on Will precautions be taken to protect anonymity of subjects are minors) Yes westing anonymity of subjects are minors) Yes No	le of Study <u>Study of abso</u>	rplior	1	Proje	ct status:
Cole the appropriate answer to Source of Population: NA  (a) Ill subjects Yes No  (b) Non-ill subjects Yes No  (c) Minors or persons under guardianship  Does the study involve: NA  (a) Physical risks  (b) Social Risks  (c) Psychological risks  (d) Discomfort to subjects  (e) Invasion of privacy  (f) Disclosure of information damaging to subject or others  Does the study involve: NA  (a) Use of records, (hospital, medical, death, birth or other)  (a) No change (do not fill out rest of the following (If Not Applicable write NA)  5. Will signed consent form be require  (b) From parent or guardian  (if subjects are minors) Yes  (b) From parent or guardian  (if subjects Yes  (b) From parent or guardian  (if subjects Yes  (c) Whysical risks  Yes  No  (d) Discomfort to subjects  Yes  No  (e) Invasion of privacy  (f) Disclosure of information damaging to subject or others  Does the study involve: NA  (a) Use of organs or body  fluids  Yes  No  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be  followed including  alternatives used Yes  No  (c) Physical risks  Yes  No  (c) Brom subjects  Yes  No  (b) From parent or guardian  (if subjects are minors) Yes  (b) From parent or guardian  (if subjects are minors) Yes  (b) From parent or guardian  (if subjects are minors) Yes  (b) From parent or guardian  (if subjects are minors) Yes  (b) From parent or guardian  (if subjects are minors) Yes  (b) From parent or guardian  (if subjects are minors) Yes  (c) Mubrella proposal - Initially overview (all other requirement be submitted her  Committee:  NA Umbrella proposal - Initially overview (all other requirement be submitted with individual s  NA Protocol (Required).  NA Abstract Summary (Required)  NA Procedure for maintaining conf ity  Procedure for maintaining conf ity  Ity  Abstract Summary (Required)  NA Questionnaire or interview scholowing in should be included in the abstract interview which could be conseived in the questionnaire or interview which could be conseived in the qu				(V)	•
Source of Population: NA  (a) 111 subjects Yes No (b) Non-ill subjects Yes No (c) Minors or persons under guardianship Does the study involve: NA (a) Physical risks to the subjects (c) Psychological risks to subjects (d) Discomfort to subjects Yes No (e) Invasion of privacy (f) Disclosure of information damaging to subject or others (b) Use of records, (hospital, medical, death, birth or other) (b) Use of fetal tissue or abortus (a) Nature and purposes of study (b) Procedures to be (c) Physical risks (c) Psychological risks (d) Use of records, (hospital, medical, death, birth or other) (b) Use of fetal tissue or abortus (c) Use of organs or body fluids (d) Nature and purposes of study (e) Procedures to be followed including alternatives used Yes No (d) Sensitive questions (e) Benefits to be derived (f) Right to refuse to participate or to withdraw from study (g) Confidential handling of data, Yes No (g) Composation \(\bar{k}\)/or treatment where there are risks or privacy is involved in any particular procedure Yes No (gree to obtain approval of the Ethical Review Committee for any changes		30.000	16115	( )	
(a) Ill subjects	animal models.			( )	No change (do not fill out rest of form)
(a) Ill subjects	cle the appropriate answer to	each	of	the fo	llowing (If Not Applicable write NA)
(a) Ill subjects Yes No (b) Non-ill subjects Yes No (c) Minors or persons under guardianship Yes Does the study involve: NA (a) Physical risks to the subjects Yes (b) Social Risks Yes (c) Psychological risks to subjects Yes (d) Discomfort to subjects Yes (e) Invasion of privacy (f) Disclosure of information damaging to subject or others Does the study involve: NA (a) Use of records, (hospital, medical, death, birth or other) (c) Use of fetal tissue or abortus (c) Use of organs or body fluids (d) Nature and purposes of study (e) Procedures to be followed including alternatives used Yes (c) Physical risks Yes (d) Discomfort to subjects (e) Informed consent form for pare introduced in the abstract Summary (Required).  NA (a) Use of records, (hospital, medical, death, birth or other) (a) Nature and purposes of study (c) Use of organs or body fluids (d) Procedures to be followed including alternatives used Yes (d) Procedures to be followed including alternatives used Yes (d) Physical risks (e) Prom parent or guardian (if subjects Yes (Check documents being submitted her Committee:  NA (Imbrella proposal - Initially overview (all other requirement be submitted with individual s (introduce) (Check documents being submitted her Committee:  NA (Imbrella proposal - Initially overview (all other requirement be submitted with individual s (introduce) (Check documents being submitted her Committee:  NA (Imbrella proposal - Initially overview (all other requirement be submitted with individual s (introduce) (Check documents being submitted her Committee:  NA (Imbrella proposal - Initially overview (all other requirement be submitted with individual s (introduce) (Informed consent form for pare introduce in the submitted with individual s (introduce) (Informed consent form for pare introduce in the submitted with individual s (Informed consent form for pare introduce) (Informed consent form for pare	Source of Population: NA		•	5.	Will signed consent form be required: MA
(c) Minors or persons under guardianship Does the study involve: NA (a) Physical risks to the subjects (b) Social Risks (c) Psychological risks (d) Discomfort to subjects (e) Invasion of privacy (f) Disclosure of information damaging to subject or others (d) Use of records, (hospital, medical, death, birth or other) (d) Use of fetal tissue or abortus (e) Use of organs or body fluids (f) Nature and purposes of study (g) Procedures to be followed including alternatives used (g) Physical risks (g) Confidential handling of data are privacy is involved in any particular procedure Yes (g) Confidential andling or gree to obtain approval of the Ethical Review Committee for any changes  (b) From parent or guardian (if subjects are minors) Yes Will precautions be taken to protect anonymity of subjects Yes Check documents being submitted her Committee:  NAU Mbrella proposal - Initially overview (all other requirement be submitted with individual's poverview (all other requirement be submitted her committee:  NAU Physical risks  Yes No	(a) Ill subjects	Yes	No		
(c) Minors or persons under guardianship Yes No Does the study involve: NA  (a) Physical risks to the subjects Yes No  (b) Social Risks Yes No  (c) Psychological risks to subjects Yes No  (d) Discomfort to subjects Yes No  (e) Invasion of privacy Yes No  (f) Disclosure of information damaging to subject or others Yes No  Does the study involve: NA  (a) Use of records, (hospital mithor other) Yes No  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluxds Yes No  Are subjects clearly informed about: NA  (a) Nature and purposes of study Yes No  (c) Use of organs or body fluxds Yes No  (d) Sensitive questions Yes No  (e) Physical risks Yes No  (f) Discomfort to subjects Yes No  (g) Confidential handling of data Yes No  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Genefication for the Ethical Review Committee for any changes	(b) Non-ill subjects	Yes	No		•
under guardianship Does the study involve: NA  (a) Physical risks to the subjects Social Risks (b) Social Risks Yes No (d) Discomfort to subjects Yes No (e) Invasion of privacy (f) Disclosure of information damaging to subject or others Social, medical, death, birth or other) (a) Use of organs or body fluids Yes No Are subjects clearly informed about: NA  (a) Nature and purposes of study (b) Procedures to be followed including alternatives used (c) Physical risks Yes No (d) Sensitive questions (e) Benefits to be derived (f) Right to refuse.to participate or to withdraw from study (g) Confidential handling of data, write and purpoval of the Ethical Review Committee for any changes  Mill precautions be taken to protect anonymity of subjects Yes No Check documents being submitted her Committee:  Check documents being submitted her Committee:  Check documents being submitted her Committee:  NA Umbrella proposal - Initially overview (all other requiremen be submitted with individual s  NA Protocol (Required).  NA Statement given or read to sub nature of study, risks, types ions to be asked, and right to to participate or withdraw (Re  NA Informed consent form for pare guardian  NA Procedure for maintaining conf ity  NA Questionnaire or interview sch.  If the final instrument is not converted in the abstract convered in the questionnaire or interview which could be cons.  1. A description of the areas to covered in the questionnaire or interview which could be cons.  1. A description of the areas to covered in the questionnaire or interview which could be cons.  2. Examples of the type of specific proposal - Initially overview (all other requiremen be submitted with individual s  NA Umbrella proposal - Initially overview (all other requiremen be submitted.  NA Informed consent form for pare guardian  NA Procedure for maintaining conf ity  NA Protocol (Required)  NA Informed consent form for pare guardian  NA Questionnaire or interview sch covered in the questionnaire or interview which could be cons.  1. A descriptio	(c) Minors or persons				- · · · · · · · · · · · · · · · · · · ·
Does the study involve: NA  (a) Physical risks to the subjects Yes No  (b) Social Risks Yes No  (c) Psychological risks to subjects Yes No  (d) Discomfort to subjects Yes No  (e) Invasion of privacy Yes No  (f) Disclosure of information damaging to subject or others Yes No  Does the study involve: NA  (a) Use of records, (hospital, medical, death, birth or other) Yes No  (c) Use of fetal tissue or abortus Yes No  (d) Nature and purposes of study Yes No  (d) Nature and purposes of study (Procedures to be followed including alternatives used Yes No  (e) Benefits to be derived (F) Right to refuse. to participate or to withdraw from study Yes No  (f) Compensation 8/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Gorfidential andling of data Yes No  (g) Confidential proval of the Ethical Review Committee for any changes	under guardianship	Yes	No	6.	
(a) Physical risks to the subjects (b) Social Risks (c) Psychological risks to subjects (c) Psychological risks to subjects (e) Psychological risks to subjects (e) Invasion of privacy (f) Disclosure of information damaging to subject or others (f) Dise of records, (hospital, medical, death, birth or other) (h) Use of fetal tissue or abortus (f) Use of organs or body fluids (f) Rature and purposes of study (f) Procedures to be followed including alternatives used (f) Right to refuse to participate or to withdraw from study (g) Confidential handling of data (h) Compensation \(\frac{6}{3}\) Procedure for continuation (h) Compensation \(\frac{6}{3}\) Procedure for continuation (h) Compensation \(\frac{6}{3}\) Procedure for maintaining confidence interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the question of the areas to covered in the question of privacy is involved in any particular procedure (res No (PTO))  (gree to obtain approval of the Ethical Review Committee:  Yes No (Committee:  Yes No (No No No (PTO) (Required)  Abstract Summary (Required)  NA Protocol (Required)  Abstract Summary (Required)  NA Protocol (Required)  Abstract Summary (Required)  NA Protocol (Required)  NA Distance (Right to to participate or withdraw (Required)  NA Distance (Required)  NA Prococolure (Required)  NA Distance (Right to to participate or withdraw (Required)  NA Prococolure (Required)  NA Distance (Right to to participate or withdraw (Required)  NA Distance (Right to required)  NA Distance (Right to submittee in the usubmitted with individual so to participate or withdraw (Required)  NA Distance (Right to submit		ŧ		•	
subjects Yes No (b) Social Risks Yes No (c) Psychological risks to subjects Yes No (d) Discomfort to subjects Yes No (e) Invasion of privacy Yes No (f) Disclosure of information damaging to subject or others (a) Use of records, (hospital, medical, death, birth or other) (b) Use of fetal tissue or abortus (c) Use of organs or body fluids (d) Nature and purposes of study (e) Procedures to be followed including alternatives used (f) Right to refuse.to participate or to withdraw from study (g) Confidential handling of data (h) Compensation 8/or treatment where there are risks or privacy is involved in any particular procedure Yes No (g) Gongan approval of the Ethical Review Committee for any changes.				7.	
(b) Social Risks (c) Psychological risks		Yes	No		
Constitute of including alternatives used for Procedures to be followed including alternatives used for Procedures to be genefits to be derived for participate or to withdraw from study  (g) Discolarial risks to subjects for privacy (f) Discolosure of information damaging to subject or others for subject or	(b) Social Risks	Yes			NA Umbrella proposal - Initially submit a
to subjects  (d) Discomfort to subjects Yes No (e) Invasion of privacy (f) Disclosure of information damaging to subject or others  Does the study involve: NA (a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  Are subjects clearly informed about: NA (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used (c) Physical risks (c) Physical risks (d) Sensitive questions (e) Benefits to be derived for Right to refuse, to participate or to withdraw from study (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Gonfidential approval of the Ethical Review Committee for any changes	(c) Psychological risks				
(d) Discomfort to subjects Yes No	to subjects	Yes	No		
(e) Invasion of privacy (f) Disclosure of information damaging to subject or others  Does the study involve: NA  (a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Anture and purposes of study  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used Yes No  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Gonfidential approval of the Ethical Review Committee for any changes					AIA Protocol (Required)
(f) Disclosure of information damaging to subject or others  (a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw (Re Informed consent form for subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw (Re Informed consent form for subjects closers form for pare guardian  NA  NA  NA  NA  NA  NA  NA  NA  NA  N	(e) Invasion of privacy				
tion damaging to subject or others  No  Does the study involve: NA  (a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used yelfold Sensitive questions yes No  (c) Physical risks  (d) Sensitive questions yes No  (e) Benefits to be derived (f) Right to refuse to participate or withdraw (Re No  (g) Confidential handling of data yes No  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  Ones the study involve: NA  Yes No  No  NAUTE and purposes of study, risks, types ions to be asked, and right to to participate or withdraw (Re NA  NAI Informed consent form for pare guardian  NA Procedure for maintaining conf ity  NA Questionnaire or interview sch oprior to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview which could be consent form for pare guardian  NA Questionnaire or interview sch oprior to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview which could be consent form for pare guardian  NA Questionnaire or interview sch oprior to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview and the participate or withdraw (Re NA  NA Questionnaire or interview sch oprior to review, the following in should be included in the abstract  2. Examples of the type of specific questions to be asked, and right to to participate or withdraw (Re NA  NA Unformed consent form for pare introview sch operior to review, the following in should be included in the abstract  2. Examples of the type of specific questions to be asked in the participate or with the participate or withdraw (Re NA  Procedure for maintaining c	(f) Disclosure of informa-				
ject or others  Does the study involve: NA  (a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used Yes No  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived (f) Right to refuse to participate or to withdraw (Re  (f) Right to refuse to participate or withdraw (Re  Informed consent form for pare guardian  NA  Informed consent form for pare guardian  NA  Procedure for maintaining conf ity  NA  Questionnaire or interview sch-  **If the final instrument is not coprior to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview which could be cons:  (e) Benefits to be derived Yes No  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (gree to obtain approval of the Ethical Review Committee for any changes	tion damaging to sub-				nature of study risks types of quest
Does the study involve: NA  (a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used Yes No  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived (f) Right to refuse to participate or withdraw (Re Informed consent form for subj Informed consent form for pare guardian  NA Informed consent form for subj Informed consent form for pare guardian  NA Questionnaire or interview sch '* If the final instrument is not con prior to review, the following in should be included in the abstract 1. A description of the areas to covered in the questionnaire of interview which could be conseither sensitive or which would constitute an invasion of prior 2. Examples of the type of specific questions to be asked in the graph of data, Yes No  (g) Confidential handling of data, Yes No  (g) Confidential handling of data, Yes No  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (gro)  (gree to obtain approval of the Ethical Review Committee for any changes	ject or others	Yes	No		ions to be asked and right to refuse
(a) Use of records, (hospital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation f/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Gree to obtain approval of the Ethical Review Committee for any changes					
ital, medical, death, birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (b) Use of organs or body Yes No  (c) Use of organs or body Yes No  (d) Questionnaire or interview sch ity  Adescription of the areas to covered in the questionnaire or interview which could be consent form for pare guardian  An Procedure for maintaining confity  ity  And Questionnaire or interview sch ity  Fight to final instrument is not comprison to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch ity  Informed consent form aity  An informed consent form for pare guardian  Informed consent form aity  Informed consent form aity  An informed consent form aity  Informed consent form aity  Informed consent ity  Informed consent ity					
birth or other)  (b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation 8/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (c) Use of fetal tissue or abortus  Yes No  (d) Use of fetal tissue or abortus  Yes No  (e) Use of fetal tissue or abortus  Yes No  (pro)  Yes No  Questionnaire or interview schapitor to review, the following in should be included in the abstract to covered in the questionnaire or interview schapitor to review, the following in should be included in the abstract to covered in the questionnaire or interview schapitor to review, the following in should be included in the abstract to covered in the questionnaire or interview schapitor to review, the following in should be included in the abstract to covered in the questionnaire or interview schapitors to review, the following in should be included in the abstract to covered in the questionnaire or interview schapitors to review.  1. A description of the areas to covered in the questionnaire or interview schapitors to review.  2. Examples of the type of specific questions to be asked in the great of the for review.  3. An indication as to when the or naire will be presented to the for review.  (pro)	ital, medical, death.				
(b) Use of fetal tissue or abortus  (c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Gree to obtain approval of the Ethical Review Committee for any chances		Yes	No		
abortus  (c) Use of organs or body fluids Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (c) Use of organs or body fluids  Yes No  ity  NA Questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in heabstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview schules  * If the final instrument is not constitute an invasion of privacy in the privacy	(b) Use of fetal tissue or				
(c) Use of organs or body fluids  Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Isse of organs or body fluids  Yes No  * If the final instrument is not conprion to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not conprion to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not conprion to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not conprion to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not conprion to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not conprion to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire or interview sch.  * If the final instrument is not constitute an invasion of privacy in the questionnaire or interview.  1. A description of the areas to covered in the questionnaire or interview, the following in should be included in the abstract and the privacy in the questionnaire or interview, the following in the questionnaire or interview, the following in the privacy in the questionnaire or interview.  1. A description of the are		Yes	No		
fluids  Are subjects clearly informed about: N \( \)  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation \( \)/(A \) or treatment where there are risks or privacy is involved in any particular procedure Yes No  (a) Yes No  (b) Procedures to be followed about: N \( \)  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (g) Confidential handling of data  (h) Compensation \( \)/(A \) or treatment where there are risks or privacy is involved in any particular procedure Yes No  (pro)  * If the final instrument is not comprise to review, the following in should be included in the abstract  1. A description of the areas to covered in the questionnaire of interview which could be considered in the abstract  2. Examples of the type of specific questions to be asked in the areas.  3. An indication as to when the or naire will be presented to the for review.  (pro)	(c) Use of organs or body				
Are subjects clearly informed about: NA  (a) Nature and purposes of study  (b) Procedures to be followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (a) Nature and purposes of study  Yes No  (b) Procedures to be covered in the questionnaire interview which could be considered in the second constitute an invasion of privacy.  2. Examples of the type of specific questions to be asked in the second constitute an invasion of privacy.  3. An indication as to when the considered in the second constitute an invasion of privacy.  4. A description of the areas to covered in the questionnaire interview which could be considered in the second constitute an invasion of privacy.  5. Examples of the type of specific questions to be asked in the second constitute an invasion of privacy.  6. Examples of the type of specific questions to be asked in the second constitute an invasion of privacy.  7. Examples of the type of specific questions to be asked in the second constitute an invasion of privacy.  8. An indication as to when the constitute will be presented to the for review.  9. An indication as to when the covered in the questionnaire interview which could be considered in the questionnaire interview which could be considered in the questionnaire interview which could be considered in the covered in the questionnaire interview which could be considered in the second constitute an invasion of privacy.  8. Examples of the type of specific questions to be asked in the second constitute an invasion of privacy in the following in the covered in the co		Yes	No		
(a) Nature and purposes of study  Yes No  (b) Procedures to be followed including alternatives used  (c) Physical risks  Yes No  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to participate or to withdraw from study  (g) Confidential handling of data  (h) Compensation \$\frac{1}{2}\$ or treatment where there are risks or privacy is involved in any particular procedure  (a) Nature and purposes of should be included in the abstract  1. A description of the areas to covered in the questionnaire of interview which could be considered in the questions are on situte an invasion of privacy areas.  2. Examples of the type of specific questions to be asked in the abstraction of the areas to covered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questions of privacy is presented to the formation of the saked in the abstraction of the areas to covered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered to a provide in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the questionnaire of interview which could be considered in the could be considered.	Are subjects clearly informe			иÅ	
study  (b) Procedures to be followed including alternatives used Yes No constitute an invasion of privacy is involved in any particular procedure Yes No  (c) Physical risks Yes No constitute an invasion of privacy is involved in any particular procedure Yes No  (d) Sensitive questions Yes No constitute an invasion of privacy is involved in any particular procedure Yes No  1. A description of the areas to covered in the questionnaire of interview which could be considered in the questions of the type of specific questions to be asked in the graph of the type of specific questions to be asked in the graph of data.  (a) Sensitive questions Yes No questions to be asked in the graph of data areas.  An indication as to when the considered for review.  (b) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No (PTO)	(a) Nature and purposes of		-		
(b) Procedures to be followed including alternatives used Yes No (c) Physical risks Yes No (d) Sensitive questions Yes No (e) Benefits to be derived Yes No (f) Right to refuse to participate or to withdraw from study Yes No (g) Confidential handling of data (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (g) Constitute an invasion of privacy of the type of specific questions to be asked in the same areas.  An indication as to when the constitute an invasion of privacy is involved in any particular procedure Yes No  (pro)		Yes	No		
followed including alternatives used  (c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to  participate or to withdraw from study  (g) Confidential handling  of data  (h) Compensation 6/or treatment where there are risks  or privacy is involved in  any particular procedure Yes No  (g) Godian approval of the Ethical Review Committee for any changes	(b) Procedures to be				
alternatives used Yes No either sensitive or which would sensitive questions Yes No constitute an invasion of privacy is involved in any particular procedure Yes No either sensitive or which would constitute an invasion of privacy is no constitute an invasion of privacy and invasion of privacy is no constitute an invasion of privacy and invasion of privacy is no constitute an invasion of privacy and invasion of privacy areas.  2. Examples of the type of specific questions to be asked in the same areas.  3. An indication as to when the considered will be presented to the for review.  (b) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No (PTO)					
(c) Physical risks  (d) Sensitive questions  (e) Benefits to be derived Yes No  (f) Right to refuse to  participate or to with- draw from study  (g) Confidential handling  of data  (h) Compensation 6/or treat- ment where there are risks  or privacy is involved in any particular procedure Yes No  (g) Constitute an invasion of privacy is involved in any particular procedure Yes No  (c) Examples of the type of specific questions to be asked in the same areas.  3. An indication as to when the continuous will be presented to the for review.  (d) Sensitive questions  questions to be asked in the same areas.  3. An indication as to when the continuous will be presented to the for review.  (e) Benefits to be derived Yes No  (g) Confidential handling  of data  Yes No  (h) Compensation 6/or treat- ment where there are risks  or privacy is involved in any particular procedure Yes No  (PTO)		Yes	No		
(d) Sensitive questions Yes No  (e) Benefits to be derived Yes No  (f) Right to refuse to  participate or to with- draw from study  (g) Confidential handling of data  (h) Compensation {/or treat- ment where there are risks or privacy is involved in any particular procedure Yes No  (g) Sensitive questions  2. Examples of the type of specific questions to be asked in the sareas.  3. An indication as to when the contained will be presented to the for review.  (g) Confidential handling of data Yes No  (h) Compensation {/or treat- ment where there are risks or privacy is involved in any particular procedure Yes No  (PTO)					
(e) Benefits to be derived Yes No questions to be asked in the second areas.  participate or to with- draw from study Yes No naire will be presented to the for review.  (g) Confidential handling for review.  (h) Compensation %/or treat- ment where there are risks or privacy is involved in any particular procedure Yes No (PTO)  (gree to obtain approval of the Ethical Review Committee for any changes					
(f) Right to refuse to  participate or to with- draw from study  (g) Confidential handling of data  (h) Compensation 6/or treat- ment where there are risks or privacy is involved in any particular procedure Yes No  (pto)  (gree to obtain approval of the Ethical Review Committee for any changes	(e) Benefits to be derived				
participate or to with- draw from study  Yes No  (g) Confidential handling of data,  Yes No  (h) Compensation 6/or treat- ment where there are risks or privacy is involved in any particular procedure  Yes No  (PTO)			.,.		
draw from study  (g) Confidential handling  of data  Yes No  (h) Compensation 6/or treat-  ment where there are risks  or privacy is involved in  any particular procedure Yes No  (PTO)  (gree to obtain approval of the Ethical Review Committee for any changes	• •			•	
(g) Confidential handling for review.  of data Yes No  (h) Compensation 6/or treatment where there are risks  or privacy is involved in any particular procedure Yes No  (PTO)  Igree to obtain approval of the Ethical Review Committee for any changes		Yes	No		
of data Yes No  (h) Compensation 6/or treatment where there are risks or privacy is involved in any particular procedure Yes No  (PTO)  (PTO)					
(h) Compensation &/or treat- ment where there are risks or privacy is involved in any particular procedure Yes No  (PTO)  (PTO)		Yes	No		TOT TEATEM!
ment where there are risks or privacy is involved in any particular procedure Yes No  (PTO)  (PTO)					
or privacy is involved in any particular procedure Yes No  (PTO)  Igree to obtain approval of the Ethical Review Committee for any changes	ment where there are ri	sks			,
any particular procedure Yes No (PTO)  gree to obtain approval of the Ethical Review Committee for any changes					
gree to obtain approval of the Ethical Review Committee for any changes			s Nr	ו	(Pario )
gree to obtain approval of the Ethical Review Committee for any changes . Uving the rights and welfare of subjects before making such change.	· · · · · · · · · · · · · · · · · · ·				
IVING the rights and welfare of subjects before making such change.	gree to obtain approval of t	ne Et	hica	l Revi	ew Committee for any changes
11 O	olving the rights and welfare	of su	ıbjec	cts bef	ore making such change.

## SECTION I : RESEARCH PROTOCOL

Title

: Study of absorption promoting oral rehydration solutions in animal models.

Principal Investigator

: Ms.Sufia Islam

Co-Investigators

: 1. Mr.M.A.Wahed Head, Biochemistry & Nutrition, ICDDR, B

2. Dr.A.S.M.Hamidur Rahman Chief, Research & Treatment Section, Animal Resources Branch, ICDDR, B

Supervisors

- : 1. Dr.D'.Mahalanabis Associate Director, Clinical Sciences Division, ICDDR, B
  - 2. Professor A.K.Azad Chowdhury Department of Pharmacy University of Dhaka

Starting Date

: April 1, 1990

Completion Date

: March 31, 1991

Total Direct Cost

: US\$ 8,428

Scientific Programme Head

: This protocol has been approved by the Clinical Sciences

Division

nature of Chairman

partment of Pharmacy versity of Dhaka

(thylenon

Congressed of Pharman University of Obaka RAHIGUADESH

Signature of Associate

Director, CSD ICDDR, B

30.1.90.

## 3. Abstract Summary

Glucose-linked enhanced sodium and water absorption from the small intestinal lumen remains largely intact during acute diarrhoea of diverse aetiology and forms the scientific basis of oral rehydration therapy (ORT). Subsequently, ORT has been developed as a powerful intervention for the treatment of dehydration due to acute diarrhoea, an invaluable public health tool, and an essential component of primary health care. The oral rehydration salts solution (ORS) recommended by WHO contains glucose (20 g) and three salts-sodium chloride (3.5 g), trisodium citrate, dihydrate (2.9 g) or sodium hydrogen carbonate (2.5 g), and potassium chloride (1.5 g), to be mixed in one litre of water. This solution has been used in the treatment of acute diarrhoeal illness for over a decade.

Studies have shown that almost all water soluble organic molecules can enhance the absorption of sodium from the small intestine. Examples are D-hexoses, neutral amino acids, dipeptides and tripeptides of neutral amino acids and some water soluble vitamins. It has been hypothesised that optimum exploitation of this phenomenon could lead to the development of an improved ORS formulation that would not only successfully replace the deficit of salts and water in diarrhoea, but also actively induce the reabsorption of endogenous intestinal secretion and thus reduce the volume and duration of diarrhoea. The proposed study intends to examine the net absorption of an ORS containing salts and selected organic solutes in rat and rabbit intestine. The type and combination of organic solutes will be varied to optimise absorption. Candidate organic solutes will include glucose, 1-alanine, glutamine, and peptides of alanine and glutamine. Polyethylene glycol (Mol. wt. be used as a non-absorbable marker. The outcome measures will include the magnitude of net absorption of salts and water. Results may be useful in further improvement of the absorption efficiency of ORS formulations.

# SECTION II : RESEARCH PLAN

### A INTRODUCTION

1. Objectives and specific aims

#### bjectives

Absorption promoting oral rehydration solution (ORS) could lead to the development of an improved formulation of ORS. Such an ORS formulation would successfully replace the deficit of salts and water in diarrhoea, induce the reabsorption of endogenous intestinal secretion, and thus reduce the volume and duration of diarrhoea. The reduced severity and duration of diarrhoea will also make it possible to introduce early a liberal and more effective feeding regime. Therefore, the nutritional benefit would be another potential advantage of the intended improved formulation of ORS.

organic nutrients likely to be of value in absorption efficiency of oral rehydration solution will be evaluated, in an in vivo study in animals e.g. rabbits and rats using ligated small intestinal loops. The components will include amino acids like l-alanine, l-glutamine, peptides and will be compared with glucose. The results of the study will be used to predict a likely formulation, which will absorption efficient than the solution containing Such formulation can then be evaluated in subjects with diarrhoea.

## <u>pecific aims</u>

Study of the absorption of water and sodium from a solution containing:

- 1. 1-alanine compared to glucose eletrolyte solution;
- 2. 1-glutamine compared to glucose electrolyte solution;
- combination of alanine and glutamine compared to glucose electrolyte solution;
- 4. combination of glucose and alanine compared to glucose electrolyte solution; and
- 5. dipeptides of glucose and alanine compared to glucose electrolyte solution.

## . Background

Stimulation of sodium absorption across the small intestinal mucosa by glucose was looked at by physiologists (Schultz and Zalusky 1964; Barry et al 1965<sup>2</sup>). <u>In vivo</u> studies in normal human intestine defined the quantitative relationships of glucose linked enhanced sodium and water absorption (Malawer et al 1965<sup>3</sup>; Levinson and Schedl 1966<sup>4</sup>; Fordtran et al 1968<sup>5</sup>).

During the phase of active purging in adult cholera patients, fluid and electrolyte losses were adequately replaced by optimally constituted oral electrolyte solutions containing glucose (Pierce et al 1968 a  $^6$ , 1968 b  $^7$ , 1969 Hirschhorn et al 1968; Nalin et al 1968 $^{10}$ ). Radioactive tracer studies in cholera patients also showed that glucose (2 g/100 ml) induces net absorption of sodium and water from the small intestine (Taylor et al 1968 $^{11}$ ).

The introduction of oral glucose electrolyte solutions for the treatment of dehydration due to acute diarrhoeas has been a major therapeutic advance of this century. The initial success of oral rehydration therapy (ORT) in adult cholera patients was tested by its vigorous application in treating diarrhoeal disease of diverse aetiology, in various age groups of infants and children. ORT emerged as a powerful therapeutic tool with the ability to correct dehydration due to acute diarrhoea in all but the most severe cases, and in all ages irrespective of aetiological agents (Mahalanabis 1984 12).

One major area of interest and scientific controversy is the substrate or carrier molecule used in ORS. Sucrose, which in many countries, is a less expensive and more easily obtained sugar than glucose, has proved a possible substitute for glucose. However, a marker perfusion study in rat (Patra et al 1982<sup>13</sup>) showed that an isosmotic sucrose containing electrolyte solution induces a significantly greater Na<sup>+</sup>, Cl<sup>-</sup> and K<sup>+</sup> absorption compared to glucose electrolyte solution. And the water absorption decreases by 14% due to the osmotic drag of water back into the lumen by the slowly absorbed fructose from the hydrolysis of sucrose.

Use of molasses with common salts simplified ORS with a minimum loss of efficacy. ORS formulations containing 30-50g cooked rice powder (Molla et al 1982<sup>14</sup>; Patra et al 1982<sup>15</sup>) in place of glucose was found to be effective. Cereal-based ORS has been shown to be effective, acceptable, and even superior to standard glucose ORS ip reducing the duration and severity of diarrhoea (Patra et al 1982<sup>15</sup>; Molla et al 1985<sup>20</sup>).

In 1984, encouraged by results from several clinical trials, the diarrhoeal disease control programme of the World Health Organisation began supporting research projects on developing improved oral rehydration solution formulations (World Health Organisation. Sixth programme report 1986-1987). Their aim is to compare the standard WHO ORS with other formulations that have the same concentration of salts but may be more effective (1). There are two types of alternative formulation. One type contains glucose or a glucose polymer and an aminoacid or peptide, or both, in varying concentrations (1): this approach was stimulated by studies in children (Patra et al 1984) and adults (Nalin et al 1970) that used formulations containing glucose and glycine. In the other type of formulation glucose is replaced by a staple food (cereals, legumes, or roots) as a source of starch and protien: this approach was based on studies that showed that a rehydration solution containing 50 or 80g of rice powder per litre in place of glucose can reduce stool volume substantially (Patra et al 1982); Molla et al 1985).

Oral rehydration solution containing 1-alanine was considerably better than standard oral rehydration solution at reducing the severity of symptoms and the need for fluid of male patients with diarrhoea associated with *Vibrio Cholera* and enterotoxigenic *Escherichia Coli* (Patra et al 1989<sup>21</sup>).

Therefore, the proposed study intends to examine the net absorption of an ORS containing salts and organic solutes (glucose, l-alanine, l-glutamine, and peptides of alanine and glutamine) in rat and rabbit intestine.

#### 3. Rationale

The review of theoretical and practical issues surrounding the choice of carrier substances used in ORS suggests that further improvement in the current formulation of ORS for acute diarrhoeal illness is needed. An attempt to increase the efficacy earlier, oral necessary. As stated therefore rehydration solution containing 1-alanine was considerably better rehydration solution (Patra et al 1989<sup>2</sup> standard oral An improved ORS formulation will successfully replace the deficit of salts and water in diarrhoea and will induce the reabsorption of endogenous intestinal secretion, thus reducing the volume and duration of diarrhoea. Such formulation would also offer nutritional benefits and simplicity of management.

#### B. METHODS

New Zealand white rabbits raised in laboratory environment (av. wt. 1.5 kg) and normal male albino rats (av. wt. 175 g) will be used for the study.

A ligated static loop (10-12 cm long) of small intestine will be constructed after opening the abdomen with a midline incision. The loop which includes jejunum, and ileum will be used to observe net absorption of a solution containing salts and selected organic solutes. Polyethylene glycol (mol. wt. 4,000) will be used as a non-absorbable marker. After injection of the solution the animal will be kept under observation for a specified interval.

After removal of the fluid, the fluid will be analysed for PEG, sodium, potassium, chloride and osmolality and compared with an aliquote of the solution before injection and the net absorption of ORS will be calculated.

The detailed procedures are given below.

# 1. Construction of the loops

Weight of the rabbit/rat will be taken. In case of rabbit after starvation of 48 hours (with free access to water), anaesthesia will be performed with intravenous pentobarbital sodium (3.25 mg/kg). Midline incision will be given to perform laparotomy; during the experiment body temperature will be maintained by using a lamp. Gently pulled small intestine from the abdominal cavity will be washed with the wash solution (NaCl 120 mmol/l, KCl 4 mmol/l), at a temperature of  $37^{\circ}\mathrm{C}$ . Then the static loops and the interloops will be constructed from the distal to the proximal part (excluding 10-15 cm distal ileum) which include ileum and jejunum.

In case of rat after 24 hours fast (with free access to water), anaesthesia will be performed with intraperitoneal sodium pentobarbital (40 mg/kg), static loops and interloops will be constructed from the proximal to the distal part of the intestine which include jejunum and ileum.

## 2. Injection of the solution

The test solutions will be injected from the distal to the proximal part of the intestine at a temperature of  $37^{\circ}$ C. The solution will contain mmol/l Na<sup>+</sup> 120, K<sup>+</sup> 4, Cl<sup>-</sup> 124 and PEG (mol. wt. 4,000) 2 g/l. In addition to it the solution will contain 50 mmol/l of selected organic solutes. The intestine will be returned to the peritoneal cavity and abdomen will be closed. The animal will be kept under observation for specified intervals.

#### 3. Removal of the solution

After the observation period the animal will be anaesthetised and the peritoneal cavity will be opened. The solution from each loop will be removed by syringe and the amount of solution will be recorded for each loop. The solutions will be collected in separate containers for estimation of PEG, sodium, potassium, chloride and osmolality. Finally the animal will be sacrificed and the intestinal loops will be removed. After stripping the excess mesentery, length of the loops will be measured (Patra et al 1982).

## Estimation of polyethylene glycol

Turbidimetric analysis of polyethylene glycol will be done on the development of an oil in-water emulsion when exposed to trichloroacetic acid in the presence of barium ion (Hyden 1955<sup>23</sup>). The optical densities of the standards and the samples will be run against the blank, using a SP8-400 uv/vis spectrophotometer (PYE UNICAM) set at a wavelength of 500nm. A standard curve will be constructed and the unknown samples will be read from the graph.

## . Measurements of electrolytes

 ${\rm Na}^+$ ,  ${\rm K}^+$  and  ${\rm Cl}^-$  will be measured by ISE (Beckman system E4A $^{\rm TM}$ ) Electrolyte analyser. The system E4A determines sodium, potassium and chloride by measuring electrolyte ions in solution. For sodium, potassium and chloride this is accomplished by using ion-selective electrodes for each of these ions.

# . Measurement of osmolality

Osmolality of the samples will be measured by freezing point depression using an advanced TM osmometer.

#### Calculations

Net transport of water and electrolytes and sugars will be calculated from the changes in the PEG concentration and the solute concentration (Levinson and Schedl 1966<sup>4</sup>).

Calculations will be performed in the following way:

- 1. PEG ratio (PEG R) =  $[PEG_T]/[PEG_F]$ I and F refers to initial and final concentrations
- 2.  $H_2O$  absorption, % = 100(1-PEG R)
- 4.  $Na^{+}(or K^{+})$  absorption, qmoles/hr  $= [Na^{+}_{I} (Na^{+}_{F} X PEG R)] X amount$ of solution injected
- 5. C1 absorption,  $qmoles/hr = [C1_I^-(C1_F \times PEG R)] \times amount of solution injected$

## 8. Data analysis

Electrolyte absorption mediated by different organic solutes will be compared

by t test for independent samples and

by its nonparametric equivalent (Mannwhitney U test)

Significance of the difference will be assessed (P<.05).

#### C. SIGNIFICANCE OF THE WORK

Reduction of the volume and duration of the diarrhoea by using an improved ORS formulation will greatly simplify the management of dehydration due to acute diarrhoea. This study will examine the net intestinal absorption of different improved ORS formulations and eventually lead to the development of an optimum absorption promoting ORS.

Results of this study will improve our knowledge on the ability of a few potentially important organic nutrients in stimulating absorption of salts and water under <u>in vivo</u> conditions in suitable animal models. These information will be of use in designing and formulating absorption efficient oral rehydration solution which can then be tested in human subjects.

# D & E. FACILITIES REQUIRED AND COLLABORATIVE ARRANGEMENTS

ICDDR,B shall provide all the laboratory facilities required for the estimation of PEG, measurement of electrolytes and osmolality. The animal resources branch of ICDDR,B will be utilised for the study in animal models.

This is a collaborative study between Department of Pharmacy, University of Dhaka and ICDDR, B. The PI is an M.Phil student of Dhaka University and shall carry out the study at ICDDR, B under the direct supervision of Dr.Dilip Mahalanabis. The study report will eventually be partial fulfilment of the requirement for her M.Phil degree.

# SECTION III: BUDGET

#### Personnel services

Name T				onorar 	ium/Salary US\$ 	P.A 
Dr.D.Mahalanabis		5%		,	_	
Professor A.K.Azad Chowdhury	/	5%		į	<b>-</b> .	
Mr. M.A. Wahed		5%			_	
Dr. A.S.M.Hamidur Rahman		5%			<del>an</del> a	
Research Fellow (PI)	11	00%			1600	
Animal Technician		5%			_	
Animal Attendent		5%	•			
2. <u>Supplies and materials</u>			Sub-t	otal:	1600	
<ul> <li>a. Disposable syringe, Need Glassware etc.</li> </ul>	dle,				200	
b. Chemicals and reagents a laboratory tests PEG Electrolyte and osm		lity			1035 3315	
c. Animals Rabbits Rats		\$ 19.80X \$ 1.76X		= =	990 88	
Animal maintenance					100	
d. Computer analysis and d	ata	entry			500	
3. Transport and conveyance					200	
4. Overhead, contingency an stationary					400	
Grand total				US\$	8,428	

## **BUDGET SUMMARY**

\_\_\_\_\_\_\_

Salary

Other cost

Supplies and materials

Total direct cost

1	year	project US\$	requirement
		1600	
		6228	,
		600	
	USS	8,428	

#### REFERENCES

- 1. Schultz SG, Zalusky R. Ion transport in isolated rabbit ileum.II. The interaction between active sodium and active sugar transport. *J Gen Physiol* 1964; 47:1043 59
- 2. Barry RJC, Smyth DH, Wright EM. Short-circuit current and solute transfer by rat jejunum. *J Physiol* 1965; 181:410 431
- 3. Malawer SJ, Ewton M, Fordtran JS, Ingelfinger FJ. Interrelation between jejunal absorption of sodium, glucose and water in man. *J Clin Invest* 1965; 44: 1072
- 4. Levinson RA, Schedl HP. Absorption of sodium, chloride, water, and simple sugars in rat small intestine. *Am J Physiol* 1966; 211: 939 42
- 5. Fordtran JS, Rector FC Jr, Canter NW . The mechanisms of sodium absorption in the human small intestine. J Clin Invest 1968; 47:884 900
- 6. Pierce NF, Banwell JG, Mitra RC, et al. Oral maintenance of water-electrolyte and acid-base balance in cholera: a preliminary report. *Indian J Med Res* 1968a; 56: 640 5
- 7. Pierce NF, Banwell JG, Rupak DM, et al. Effect of intragastric glucose-electrolyte infusion upon water and electrolyte balance in Asiatic cholera. *Gastroenterology* 1968b; 55: 333 43
- 8. Pierce NF, Sack RB, Mitra RC, et al. Replacement of water and electrolyte losses in cholera by an oral glucose-electrolyte solution. *Ann Intern Med* 1969; 70: 1173-81
- 9. Hirschhorn N, Kinzie JL, Sechar DB, et al. Decrease in net stool output in cholera during intestinal perfusion with glucose-containing solutions. *N Engl J Med* 1968; 279:176 81
- 10. Nalin DR, Cash RA, Islam R, Molla M, Phillips RA. Oral maintenance therapy for cholera in adults. Lancet 1968; 2: 370-3
- 11. Taylor JO, Kinzie J, Hare R, Hare K . Measurement of sodium flux in human small intestine. *J Clin Invest* 1968; 27:386
- 12. Mahalanabis D. Oral rehydration therapy. In: Chandra RK,

- ed. Critical reviews in tropical medicine. Vol. 2. New York: Plenum, 1984: 77-91
- 13. Patra FC, Mahalanabis D, Jalan KN. Stimulation of sodium and water absorption by sucrose in the rat small intestine. Acta Paediatr Scand 1982; 71: 103 7
- 14. Molla AM, Sarker SA, Hossain M, Moll A, Greenough WB III. Rice-powder electrolyte solution as oral therapy in diarrhoea due to *Vibrio Cholera* and *Escherichia Coli. Lancet* 1982; 1: 1317 9
- 15. Patra FC, Mahalanabis D, Jalan KN, Sen A, Banerjee P. Is oral rice electrolyte solution superior to glucose electrolyte solution in infantile diarrhoea? *Arch Dis Child* 1982; 57: 910 2
- 16. Molla AM, Nath SK, Molla A, Khatun M. Food-based oral rehydration salt solution for acute childhood diarrhoea. *Lancet* 1989; 2: 429 31
- 17. World Health Organisation. Sixth Programme report 1986 1987. Programme for control of diarrhoeal disease. Geneva: WHO, 1988: 42 6 (WHO/CDD/88.28)
- 18. Patra FC, Mahalanabis D, Jalan KN, Sen A, Banerjee P. In search of a super solution: Controlled trial of glycine-glucose oral rehydration solution in infantile diarrhoea. *Acta Paediatr Scand* 1984; 73: 18 21
- 19. Nalin DR, Cash RA, Rahman M, Yunus M. Effect of glycine and glucose on sodium and water absorption in patients with cholera Gut 1970; 11: 768 72
- 20. Molla AM, Ahmad SM, Greenough WB III. Rice-based oral rehydration solution decreases the stool volume in acute diarrhoea. Bull WHO 1985; 63: 751 6
- 21. Patra FC, Sack DA, Islam A, Alam AN, Majumder RN. Oral rehydration formula containing alanine and glucose for treatment of diarrhoea: a controlled trial. *Br Med J* 1989; 298:1353-6
- 22. Morin CL, Ling V. Effect of pentagastrin on the rat small intestine after resection. *Gastroenterology* 1978; 75: 224 9
- 23. Hyden SA. Turbidimetric method for the determination of higher polyethylene glycols in biological materials. *Kgl Lantbrunks Hogsk Ann* 1955; 22: 139 45