PERFORMAS FOR MOVEMENT OF REGULATED MATERIALS



Application for Permission for the Movement of Regulated Materials

1	Name and full professional address of Applicant.	2 P	ermission Requested	This Request is)	
		Limited	In-Country Movement []	New []	
		Limited	- Importation []	Renewal []	
				Supplemental []	
Tel: Fax: Emai	1	5 Permission Pequested ("X" one) Mail [] Baggage or handcarried [] Common carrier [] By Whom			
6	Give the following (if applicable) if more	space is n	eeded attach additional sheet)		
a.	Donor Organism	scientific Nar	me <u>Common Name</u> <u>Trade</u>	Name Other Designation	
	Recipient Organism				
c.	Vector or Vector Agent				
d.	Regulated Organism or Product				
e.	If product, list names of constituents				
7	Quantity of regulated article to be introduced proposed schecule and number of introduction		8 Date (or inclusive dates movement	of period) of importation or in country	
9	Country or point of origin of the regulate	ed article	10 Port of arrival/destina	tion movement or specific location.	
	country or point or origin or the regular		10 1000 1111111111111111111111111111111	som movement or specific rotations	
11	Any biological material (e.g. culture medium,	or host ma	nterial) accompanying the regulated	article during movement.	
12	State why you believe the organism or p	roduct do	es not come within the defination	n of a regulated article.	
13	Certificate: I hereby certify that the information knowledge and belief	tion in the	application and all attachments is co	omplete and accurate to the best of my	
14	Signature of Applicant 15	Print	ted name and title	16 Date	



Application for Permission to Import or Transport Organisms or Vectors

1 Mode of transportation (Please circle).	Port of Entry	
AIR SEA LAND ANY		
3 IMPORTER: (Name, complete address, telephone and fax number).	4 SHIPPER: (Name and address of foreign producer)	
<u> </u>		
Tel:	Tel:	
Fax:	Fax:	
Email	Email	
2		
DESCRIPTION (material, country of origin, animal sorpreparation, antibody immunogens etc. (COMPLETE VS	urce, recombinant system & genetic inserts conditions of imported FORM 16-7 for all cultures & their.	
•		
Quantity and frequency of importations (estimate)		
()		
Proposed use of material expected completion date, and fin	nal disposition (method)	
8 Description of applicants facilities and equipment for hand	Iling	
Qualifications of technical personnel working with this ma	terial (if applicable)	
10 Treatment of material prior to importation (processing/pu	rification methods, treatments, disease safeguard, etc.)	
The state of the s		
Work objectives, proposed plan or work, and additional p	ertinent information (animal model, use of derivatives, etc.)	
Pertinent Published Paper/Abstract regarding material to be imported – attach copy, if available		
and oppy a manage		
Certificate: I hereby certify that this material will be used in accordance with all restrictions and precautions as may be specified in the permit		
14. Signature of Applicant 15. Printed name	e and title 16. Date	



Application for Permission to Import or Transport Plants or Plant Products

PLANTS OR PLANT P	RODUCTS TO BE IMP	ORTED		
COUNTRY OF ORIGIN Make separate entry for each Country).	Scientific (Botan (cilloguial names A plants, cuttings, c	AME OF PLANTS OI nical) or English names re not acceptable) List ut flowers, fruits, etc. I (consumption, or other	whether seeds, bulbs, ndicate whether for	PAKISTANI PORT OR PORTS OF ARRIVAL
se additional pages if more space	l is needed and "X" box	; 🛮		
MEANS OF IMPORTATION		nil or Parcel Post e Mail or Parcel Post	Air Freight Truck, Rail, or Sh	[] Car [] ip [] Baggage []
Approximate Date Of Depa	arture For Pakistan	Arrival Date	4 Are Other I: The Next T	mportation Contemplated Within wo Years
ANSWER 6, 7, AND 8 ONLY IF	F IMPORTED MATERI	AL WILL BE RESHIE	PED TO ANOTHER CO	DUNTRY
Reshipment will be by		AIR []	WATER []
6 Port of exit from Pakistan 7 Country of final destination.				
8 NAME AND ADDRESS C	OF APPLICANT			
Signature of Applicant		Telephone	Telephone No.	Email Address

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED LIST DATE & PERMIT NO.
a	Names, addresses, and telephone number of the persons who developed and/or supplied the regulated article.		
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the nomodified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics).		
c.	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article.		
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.		
e.	A detailed description of the purpose of the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.		
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in Pakistan to prevent contamination, release, and dissemination in the production of the donor organism; recipient organism; vector or vector agent; constituents of each regulated article which is a product; and regulated article.		
g.	A detailed description of the intended destination (including final and all intemediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).		
h.	A detailed description of the procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.		
i.	A detailed description of the proposed method of final disposition of the regulated article.		

\mathbf{D}	NΙ
IDC.	NO.



Application for Permission to Import or Transport Mammalian Cell Line

import or rranspo	ort Mainmanan Cen Line
1 Cell line or reference No.	2 Country of origin of cell line
3 Cell line passage history	For hybridoma specify immunogen & fusion partners
cen me passage instory	Tot nyortaona speerly inmanagen & tusion partners
5 For others specify origin or derivation (e.g. EBV	V transformation)
	gen sources used and/or added). Specify <u>country of origin</u> particularly origin
(include species) supplements or nitrogen sources.	
7 Country or origin and source of enzymes used	l (e.g. typsin).
Country of origin and source of enzymes used	- (~18· -\$1pam).
Nome of any animal viruses studied in the lab	where the cell line originates
8 Name of any animal viruses studied in the lab	where the cen line originates
Address of lab where material originated (if di	ifferent from shipping lab)
10. If recombinant specify genetic insert.	
11 Potential use of imported cells or products (us	e of derivatives or extracts, immunogen for antibodies produced and production
method	
18 Name & Signature of applicant	
	<u> </u>
	Date / /

IBC	Nο
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IBC Permission

For Movement of regulated	To Import or Transport Plant or Plant Products	To Import or Transport	To Import or Transport Mammalian Cell Line
materials	Plant or Plant Products	Organisms or Vector	Mammalian Cell Line
	1		
1 IBC Review).			
2 Specific Comments			
3 Permission [] with]	Provisos []		
4 Signature of IBC Se	ecretary.		

Date

PERFORMAS FOR

PROJECT PROPOSAL FOR PERMISSION TO UNDERTAKE LABORATORY GENETIC MANIPULATION WORK

IBC No.	
IBC No.	



Cover Sheet

Project Proposal for Permission to Undertake Laboratory Genetic Manipulation Work

1	Name and full professional address of Principal Investigator submitting proposal.	2	Name(s) of other Principal Investigators responsible for the project. Please give their professional addresses if different from that in '1'.
Tel: Fax: Emai	ı	Tel: Fax: Ema	: :
3	Title of Project.		
4	Intended date of commencement		
5	Expected date of completion. Into which category does this work fall?	Cate	tegory 1 [] Category 2 [] Category 3 []
6	Main Goals		
7	Quantify goals requiring approval		
i)			
ii) iii)			
iv)			
v)		•	1
8	Signature of Principal Investigator submitting th	is proj	pposal. Date / /

Section A - Introduction

9.	Proj	ect Title				
	•	Rationale of Studies				
10.	Proj	ect Objectives				
	•	Overall Objective Specific Objectives i) ii) iii)				
	•	Objectives during 1st Year				
			0	12	24	36
	•	Time Schedule Objective-1 Objective-2 Objective 2		Mont	hs	
11.						

12. Intended Classification

Category 1 [] Category 2 [] Category 3

13. Any special precautions/safeguards to be adopted.

Section B - Materials and Methods

- 14. Details of the Biological System.
 - A. The Origin of donor DNA. Donor organism's geographical distribution, natural habitat, natural predators etc.
 - B. Characteristics of the donor DNA.
 - C. Description of Host Organisms or Tissues.
 - D. Description of Vectors or Methods for transfer of donor DNA into the Host. Degree of relatedness between host and donor.
 - E. Characteristics of the Host/Vector System(s), as applicable.
 - Predicted Stability of Introduced Genetic Traits.
 - Identification Characteristics or Markers.
 - F. Auto-Ecology of each host/vector system
 - Viability in Open Environment.
 - Possibilities of Crossing to Related and Other Species.

15.	History of Prior Work with Components of the Biological System.
16.	 Laboratories and Facilities where work will be conducted (for each investigator) Complete Address of location of the laboratory in which work to be Conducted. Level of Physical Containment (Biosafety). [] C1
17.	Additional information that will be helpful in risk assessment of the Project.
Sectio	on C - Personnel Involved with Research Work Proposed
18.	 Details of Personnel. Name, Qualification and Experience. Responsibilities and Duties. Medical History. ementary Information only for Work on Whole Plants
19.	A. Are the experimental plants noxious weeds [] Yes [] No If yes, elaborate on the ecological content: • Reproductive Cycle and Evolutionary Potential. • Dispersal, Proliferation and Persistence in Open Environments. • Factors which might limit growth, reproduction and survival. • Natural Crossing Possibilities to wild populations. • Noxious Characteristics.
	 B. Are the experimental plants closely related to noxious weeds? Yes No If yes, indicate species/strains/natural variants; and elaborate on the ecological context of each: Reproductive Cycle and Evolutionary Potential. Dispersal, Proliferation and Persistence in Natural Habitats. Factors which might limit growth, reproduction and survival. Natural Crossing Possibilities (particularly to experimental plants). Noxious Characteristics. C. Are microorganisms involved in these studies. If so, are they harmful to humans, plants or animals?
	[] Yes [] No

If yes, elaborate on the harmful agent (e.g. pathogenic or infectious determinant? toxic substance?) and the known or likely modes of transmission.

Indicate any potential to cause epidemics.

20.	Further	Details	of the	Method	dology.
-----	---------	---------	--------	--------	---------

A.	Substrate for use in cultivation?		
	[] Soil[] Soil Substitute (specify)		
	Describe the sterilization procedures.		

- B. Plans for Cultivation of Genetically Manipulated Plants.
 - Developmental Stage(s) Targeted and Intentions to Breed.
 - Arrangements for containment of plants and plant materials (spores, seeds, pollen, vegetative materials).
 - Arrangements for disposal of plants and plant materials; wastes and byproducts which may contain viable plant materials.
- 21. Details of equipment and facilities for use in cultivation.
- 22. Any additional information relevant to the assessment of this work.

Supplementary Information only for Work on Transgenic Animals

- 23. Details of the Experimental Animals.
 - A. Nomenclature.
 - Class, scientific name and strain.
 - Indicate whether a local or an exotic species.
 - B. Number of Experimental Animals. (schedule of the approx. number of animals to be handled each year and at any one time).
- C. Developmental Stages Targeted.

(stages in life cycle involved, for example, "embryo only" or "through reproductive age").

- 24. Details of the Genetic Manipulation.
 - A. Does genetic manipulation involve [] germline or [] somatic cells?
 - B. Characteristics of donor DNA.
 - Origin and construct (with reference to biological source(s) and to proposal(s) covering preparation of the DNA).

- Characterization and history of prior use in genetic manipulation (with references of published work).
- Physiological traits intended to be conferred (e.g. production of new, biologically active compounds, increased resistance, altered appearance and productivity).
- C Method for Introduction of donor DNA
 - [] electrical (specify) [] mechanical (specify)[] biological vector if a biological vector is involved, describe:
 - Construct and characterization (with references to published work and to proposal(s) covering preparation of the vector).
 - History of prior use in genetic manipulation and recommended containment level.
- D. Heredity of Introduced Traits.
 - Reproductive capacity of experimental animals.
 - Assessed heritability of transgene(s).
 - Expected form of heredity of target phenotype(s).

Note: Address Item-17-18 only if other animals will be housed in the same facilities, but for other work; otherwise "Note applicable"

- 25. Considerations in the Design of Transgenic Animal Houses and in the Choice of Animal Containment Levels.
- 26. Concurrent Use of Transgenic Animal Houses.
 - A. Number and Composition of the Other Animals. (number of animals of different species/strains).
 - B Basic Nature of the Other Work
 - Use of the other animals, for example, in infectious disease work or in separate genetic manipulation work
 - C. Arrangements to keep transgenic animals separate from the other experimental animals (physical and temporal provisions).
 - D. Arrangements to identify and to account for individual animals.
- 27. End Use, Care and Disposal.
 - A. Intentions to breed, if animals will be reared to full maturity (scheme for projected crosses).
 - B. End Use/Application of transgenic animals (only a brief description is necessary).
 - C. Arrangements for the care or disposal of transgenic animals at the conclusion of work.
- 28. Additional information, if any.
- 29. Signature (of Project Supervisor) and Date.

Prominent intents should be indicated in the title or under the objectives.



IBC Assessment of Proposal for Laboratory Genetic Manipulation Work

1	Name and full professional address Investigator submitting proposal.	of Principal	2	Name(s) of other Principal Investigators responsible for the project. Please give their professional addresses if different from that in '1'.
Tel: Fax: Email			Tel Fax Em	
3	Title of Project.			
4	Intended date of commencement. Expected date of completion.			
5	Assessment of the Project Proposal			
5.1	Project Objectives & Methodology:	Approved	[]	Not Approved [] Inconclusive [
5.2	Biological System:	Approved	[]	Not Approved [] Inconclusive [
5.3	Site or Location:	Approved	[]	Not Approved [] Inconclusive [
5.4	Safeguards and Contingency Plans:	Approved	[]	Not Approved [] Inconclusive [
5.5	Timing and Period of Work:	Approved	[]	Not Approved [] Inconclusive [
5.6	Details of Personnel:	Approved Approved Approved Approved	[] [] []	Not Approved [] Inconclusive []
6	Assessment of supplementary infor	mation on Pl	ant W	ork
7	Assessment of supplementary information	mation on A	nimals	

8	Risk category as assigned by the IBC	Category 1 []	Category 2 []	Category 3 []
9	Laboratory Containment	C1 []	C2 []	C3 []
10	Animal House Containment	C1A []	C2A []	
_11	Plant Glasshouse Containment	PH1 []	PH2 []	PH3 []
SEC	CTION B - IBC RECOMMDATION			
12	The Project has been reviewed by the IBC as work has proposed; does not endorse [] the			endorse [] the
i)	Provide additional information/documents on			
ii)	Follow conditions/amendments in your research	ch as follows		
13	The following s	pecial provisions must	be adopted	
i)				
ii)				
iii)				
iv)				
SEC	CTION C - IBC REQUESTS TAC			
14	The Project Proposal has been reviewed by the MBC specific ad	IBC and as assessed a vice/action regarding t		quires and requests
i)				
ii)				
iii)				
iv)				
_ 15	Signature of IBC Chairperson.			
			Date	/ /

SECTION D – TAC REQUESTS NBC

16	The Project Proposal has been reviewed by the IBC and the MBC and as assessed above, the Committees requires and requests specific advice/action regarding the following
i)	
ii)	
iii)	
iv)	
17	Signature of TAC Chairperson.
	Date / /
SEC	TION E
18	The NBC has reviewed the IBC/TAC assessment/request for advice and approved the following actions:
i)	
ii)	
iii)	
iv)	
19	Signature of NBC Secretary.
	Date / /

PERFORMAS FOR

PROJECT PROPOSAL FOR PERMISSION TO UNDERTAKE FIELD TRIALS

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Cover Sheet

Proposal for Permission to Conduct Field Trials

1 Re	ference numbers: (IBC numbers for p	roposals, previously submitted f	rom which this deliberate release proposal
has	developed.)		
2 Pro	ect title:		
3 Na	me of organization:		
4 Su	pervising IBC:		
5 Pro	oject supervisor:		
Name:	Ject supervisor.	Position:	
Address:			
Telephone:	Fax:		Email
C 10	cation of release:		
6 Lo	cation of release.		
7 In v	which District/Province the release v	vill take place?	
10-11			
8 Wh	en is the release to occur?		
9 Wh	en is the release expected to end?		

10	Scale of release (number of animals involved, size of plot, etc.):			
11	What is the size, scale and timing of anticipated future releases?			
40	Main objectives to be achieved from the release:			
12	Main objectives to be achieved from the release.			
13	Signature of Principal Investigator submitting this proposal.			
- 10				
		Date	/	/
		Duie	/	1

Section A - Introduction

- 14. Project Title
 - Rationale of Studies
- 15. Project Objectives
 - Overall Objective
 - Specific Objectives
 - i)
 - ii)
 - iii)
 -
 - Objectives during 1st Year

36



0

12

24

- Objective-1
- Objective-2
- Objective-3

.....

16. Intended Date of Commencement;

Expected Date of Completion.

- 17. Proposed Risk Category
 - [] Category 1 [] Category 2 [] Category 3
- 18. Anticipated Future Release and/or End Use.

Section B - Materials and Methods

- 19. Site of Field Work
 - Location of trial and how plots are to be arranged on site
 - Details of the physical environment and ecology.
 - Facilities available on site.
 - Reasons for the choice of location.
- 20. Scale of Field Work
 - Approximate number of organisms involved and the size of test plots.
- 21. Methodology and Protocol
 - Descriptions of the main experimental procedures.
 - Indicate the developmental stages involved, and identify the control, test and challenge groups.

- 22. Precautions and Safeguards (please describe in full)
 - Measures for containment of test plots and experimental organisms
 - Arrangements for the disposal of experimental organisms, and for the clean up of organic residues, at the completion of work
 - Contingency plans
- 23. Results from Laboratory Tests of the Biological System
 - A. Characterization of Genetic Modification
 - Stability of Introduced Genetic Traits
 - Heredity of Genetic Inserts
 - Level of expression and regulation of transgenes
 - Traces of recombinant vectors in the final construct (where applicable)
 - B. Effects of Genetic Modification
 - Changes in Phenotype and Novel Physiological Traits
 - C. Evolutionary Potential
 - Competitive or Selective Advantage, conferred by genetic modification.
 - Potential for Mutation and/or Adaptation to field conditions
 - D. Noxious or Harmful Characteristics
 - Nature of the Harmful Agent
 - Known and/or Likely Modes of Transmission
 - E. Ecological Context (Auto-Ecology)
 - Viability in Open Environments
 - Known predators and parasites
 - Natural Crossing Possibilities to Related Species
 - Propensity for Transfer of Genetic Inserts
- 24. History of Prior Field Work (with the experimental organism(s) or with related biological systems)
- 25. Assessed Course of Work
 - Anticipated direct, and indirect ecological effects
 - Possible secondary genetic effects

Section C - Personnel Involved with Research Work Proposed

- 26. Details of Personnel.
 - Name, Qualification and Experience.
 - Responsibilities and Duties.
 - Medical History.

DC	No
IBC.	NO.



IBC Assessment of Proposal for Field Trial

Reference numbers: (IBC numbers for proposals, previously submitted from which this deliberate				
	release proposal has developed.)			
2	Project title:			
3	Name of organization:			
4	Supervising IBC:			
	<u> </u>			
5	Project supervisor:			
Name:			Position:	
Addres	SS.:		1	
Telepho	one:	Fax:		Email
L		l		
6	Location of release:			
_	Location of foldage.			
7 In which District/Province the release take place?				
in which district flowince the release take place!				
<u> </u>				
8 When is the release to occur?				
Trilei is the release to occur:				
9	When is the release expe	cted to and	2	
9	winem is the release expe	cieu io ella	ı	

10	Scale of release (number of animals involved, size of plot, etc.):		
11	What is the size, scale and timing of anticipated future releases?		
12	IBC assessment: (Give an evaluation of the project including a comment on the project supervisor's capability to manage the work, the adequacy of the project design, site selection and contingency plans.)		
SEC	TION B - IBC RECOMMDATION		
13	The Project has been reviewed by the IBC as assessed above and the Committee does not endorses [] the work has proposed; endorses [] the work with the following provisos.		
i)	Provide additional information/documents on		
ii)	Follow conditions/amendments in your research as follows		
14	The following special provisions must also be adopted		
i)			
ii)			
ii)			
iv)			

SECTION C - IBC REQUESTS TAC

15	The Project Proposal has been reviewed by the IBC and as assessed above, to and requests MBC for specific advice/action regarding the following the specific advice/action regarding the following the specific advice/action regarding regarding regarding the specific advice/action regarding regarding regardin		ittee requires
i)			
::\			
ii) ii)			
iv)			
,			
16	Signature of IBC Chairperson.		
	Date	1	1
SECT	TION D – TAC REQUESTS NBC		
17	The Project Proposal has been reviewed by the IBC and the MBC and as a Committees requires and requests specific advice/action regarding	ssessed a	above, the ng
i)			
ii)			
ii)			
iv)			
18	Signature of MBC Chairperson.	,	,
SECT	Date TION E	1	, , , , , , , , , , , , , , , , , , ,
19	The NBC has reviewed the IBC/MBC assessment/request for advice and apactions:	proved th	e following
i)			
ii)			
ii)			
iv)			
20	Signature of NBC Secretary.		
	Date	1	1

IBC No.



Cover Sheet

Application for Commercialization of Genetically Engineered Organisms and Products Thereof

Engineered Organisms and Products Thereof			
1	Name and full professional address of Principal Investigator submitting proposal.	Name(s) of other Principal Investigators responsible for the project. Please give their professional addresses if different from that in '1'.	
Tel: Fax Em	:	Tel: Fax: Email:	
3	Name of Products		
4	Summary of Field Data:		
a)	Duration of Field Test:	b) Sites of Field Test:	
c)	Scale of Field Tests:		
d)	Description of Field Tests:		
e)	Results of Field Tests:		
f)	Conclusion of the field results:		
5 Certificate: The undersigned certifies that, to the best of his/her knowledge and belief, this application includes all data,			
information, and views relevant to the matter, whether favourable or unfavourable to the position of the undersigned, which is the subject of the application			
Signature of the Applicant:			
6	Signature of Principal Investigator submitting th	is proposal.	
		Date / /	

- 7. Rationale for Development of the Organism/Product
- 8. The Organism or its Product
 - a) Unmodified organism (e.g. cotton/rice as a crop)
 - b) Taxonomy of the organism
 - c) Genetics of the organism
 - d) Mode of reproduction
 - e) Characteristics of the unmodified organism/product

If the organism is a crop plant, please proceed to (f) and (g).

- f) Modes of gene escape in the environment
- g) Weediness (the organism is a crop or plant)
- 9. Description of the Modification/Transformation
- 10. Donor Genes and Regulatory Sequences
 - a) Gene of interest
 - b) Marker gene
- 11. Genetic Analysis of Field Performance
 - a) Souther Gel Analysis
 - b) Expression of inserted genes
 - c) Characteristics of the modification/improvement
 - d) Characteristics of the specialized feature introduced as a modification.
 - e) Mendelian inheritance
 - f) Mycotoxins (in the case of plants)
- 12. Environmental Consequences of the Modification
 - a) Specific advantages
 - b) Current uses of unmodified organism/product, normal practices and disadvantages
 - c) proposed use of the modified organism/product with economic and social advantages
 - d) Possible side-effects
 - e) affects on related organisms
 - f) Vertical transfer of the new genes
 - g) Horizontal transfer the new genes
- 13. Adverse Consequences of the Modification
- 14. References

PERFORMAS FOR SPECIFIC PROVISION TO GRANT EXEMPT STATUS

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Cover Sheet

Project Proposal Form for Requesting Exempt Status

Name and full professional address of Principal Investigator submitting proposal.	Name(s) of other Principal Investigators responsible for the project. Please give their professional addresses if different from that in '1'.	
Tel: Fax: Email	Tel: Fax: Email:	
3 Title of Project.		
4 Project Objectives		
Methodology and Protocol (i. Provide through description of the main experimental procedures; ii. Include timetable of activities.		
6 Reasons why Project Merits Exempt Status		
6 Signature of Principal Investigator submitting the	nis proposal.	
	Date / /	