Trial Manager's Handbook

Procedures and Forms
For Field Experiments with Genetically Engineered Crops

Uganda National Council for Science and Technology, 2006

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Procedures and Forms
For Field Experiments with Genetically Engineered Crops

A Guide to the Safe Conduct of Confined Field Trials
For Authorized Parties, Principal Investigators and Trial Managers

Prepared by Uganda National Council for Science and Technology

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Table of Contents

Preface

Understanding the nature of biological processes has advanced beyond observations, description of natural phenomena, growing of parts of tissues or even cell culture techniques, all of which have depended on chance and gross manipulation. Genetic manipulation techniques of biological processes at molecular level have been enhanced by Recombinant Deoxyribonucleic Acid (rDNA) technology. This has led to deliberate creation of new lines of Genetically Modified (GM) or Engineered (GE) organisms also frequently referred to as Living Modified Organisms (LMOs).

Application of rDNA in crop, animal and human growth and development systems is poised to enhance food production and security, health safety and environmental conservation and biodiversity maintenance. The rDNA technology enhances biological processes which otherwise would have taken place by chance or would be undirected, leading to timely, unacceptable and undesirable outcomes. However, directed and controlled outcomes of these processes should ensure food security, health safety and technological wellbeing of humanity. In tropical Africa where environmental risk factors have more significant influence on agriculture production, this (rDNA) technology should be carefully and systematically adopted for laboratory and green houses (contained) testing, as well as open field (but confined) trials of crops.

A systematic approach to integrated contained/confined systems requires laboratory and glass houses infrastructure as well as small scale areas of restricted access in the open field for Confined Field Trials (CFT), respectively. A CFT area avoids human and animal interference, enhances reproductive isolation, easy surveillance, removal of volunteers and management of new genetic traits of crops introduced to the geographical area. CFT therefore calls for regulation of the adoption and implementation processes in crop biotechnology, requiring governments' approval, over-seeing the implementation and evaluation processes (development of best, or elimination of poor traits among crops) as well as establishment of effective control at the local environment through Regulatory Authorities and their inspectors. Regulatory activity requires permanent well trained staff that is well guided using available publicly accessible documents. This has necessitated the production of a Trial Managers Handbook: Procedures and Forms for field experiments with GE plants.

This manual is not exclusive on its own. Users, who will find the documents useful, may adapt it to their own existing systems according to their operating structures. Your own documents may therefore prevail as these are only guidelines.

This manual is valuable to all regulators including those whose backgrounds are neither biological nor legal sciences. The primary purpose is to give a unified framework of methods, procedures, processes and suitable forms together in a comprehensive manner. The manual is now available, accessible, to expert scientists as a checklist document and to first-time users as well.

The development of this manual would not have been possible without the insight of the National Research Council of the U.S. National Academy of Science on GE's, which recommended the management of confinement through the integrated confinement system. PBS of IFPRI in Washington, D.C. which through the Donald Danforth Plant Centre in St. Louis, MO. USA, provided the resources. Dr. Mark E. Hasley of BPS – Donald Danforth Plant Centre gave the leadership of being the principal author with a team of reviewers identified in the respective manuals. PBS's East African Coordinator Dr. Theresa Sengooba provided the lead contact and organizational point for several workshops, seminars and consultations during the development of the local input and training for this program. As the Chairman of the NBC of UNCST, the Regulatory Authority of Biosafety in Uganda, I am privileged to write this preface on behalf of NBC.

While this document may not cover all areas of CFT in this edition, there will be need to update it in future and for the users to feel free to consult other sources of Biotechnology Biosafety regulatory documents and websites.

You are invited to make the best use of these manuals and feel free to notify UNCST on any improvements you may identify.

Professor John Opuda-Asibo, J., BVM (Mak) MPH, PhD (Minnesota)
Chairman NBC - Uganda

Foreword

The process of modernizing agriculture in Uganda inevitably involves the application of new farming and agro-processing technologies such as genetic engineering of crop plants to increase yield and nutritional qualities, withstand biotic and abiotic stress conditions, resist diseases and pests or to be used as bio-factories for pharmaceutical products. The generation, development and application of these genetic engineering techniques have biosafety implications, which must be carefully managed to ensure that the process and final products are safe for human consumption and the environment.

The Trial Manager's Handbook for Uganda is part of the several biosafety mechanisms that government has put in place to facilitate the testing and development of potentially useful genetically modified/engineered crop plants. This Handbook has been developed following the Integrated Confinement System approach, which guarantees that safety considerations are addressed right from the conception and inception of the trial to its completion.

Besides its use in field experiments of genetically modified plants, this Handbook also provide a useful platform, both now and in the future, for expanding and sustaining collective scientific efforts of promoting the safe application of genetic engineering techniques in agricultural production systems in Uganda.

UNCST is grateful to all its partners, especially the Program for Biosafety Systems, for the support and cooperation in building an effective and efficient national biosafety system in Uganda. We also recognize in a special way and express our gratitude to those who are contributing to agricultural modernization through application of genetic engineering.

Dr. Peter Ndemere
Ag. Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Acknowledgements

Production of this Trial Managers' Handbook containing the standard Operating Procedures for Confined Field Trials is a major step forward in making research with genetically modified plants possible in Uganda. The document was produced with contribution from a range of authorities and biosafety stakeholders in the country.

Members of the National Biosafety Committee, agricultural research scientists, and officials from the Crop Protection Department of the Ministry of Agriculture participated at various stages of preparing these manuals and their contributions and support are highly appreciated.

Special thanks go to the members of the drafting and editing team that included Dr. Mark Halsey formerly of Donald Danforth Plant Sciences Center, USA, Mr. Arthur Makara, UNCST, Ms. Grace Akao and Dr.Emmanuel Iyamulemye both of Crop Protection Department of MAAIF. Their concerted effort in putting this document together and their continuous review is greatly appreciated. In a special way, we would like to acknowledge the technical backstopping from Program for Biosafety Systems (PBS) that facilitated UNCST in its efforts to put in place this document in the effort to establish a functional Biosafety system in Uganda. Ms. Barbara Zawedde and Dr. Theresa Sengooba of PBS based at IFPRI, your input during the preparation of this document as well as the administrative role you have continued to play in this and other Biosafety related endeavors is highly appreciated. This document, we are sure, will go a long way in ensuring safe conduct of confined field research trials with genetically modified plants in Uganda.

We are highly grateful to USAID Uganda Mission for providing the financial support through PBS that enabled the production of this manual.

Definitions

Anthesis: The time when a flower, plant or crop releases pollen.

Applicant: A party submitting an application for a confined field trial. Typically, the Applicant is the same as the Authorized Party (see), or is acting in collaboration with the Authorized Party.

Authorized Party: The addressee of the Letter of Authorization is called the Authorized Party. The Authorized Party shall be a permanent resident of Uganda, or shall designate an agent who is a permanent resident of Uganda. 'Authorized Party' is construed herein to include any designated agents thereof. The Authorized Party accepts full responsibility for compliance with the Terms and Conditions of authorization, including all associated legal and financial obligations.

Compliance: Fulfilling the requirements of the Terms and Conditions of Authorization, especially with regard to confinement measures.

Compliance Infraction: Violation of the Terms and Conditions of Authorization.

Confined Field Trial (CFT): A field trial of GM plants not approved for general release, in which measures for reproductive isolation and material confinement are enforced, in order to confine the experimental plant material and genes to the trial site.

Confinement: Restriction of an organism and its genetic traits to a specific and defined area of the environment, herein called the 'confined field trial site' or the 'trial site'(see).

Construct (n): A segment of DNA to be transferred into a cell or tissue in the process of 'genetic modification' (see).

Event: A single instance of modification of a specific plant species and type using a specific genetic construct.

Facility Manager: The individual responsible for the supervision of a storage or testing facility

Following Crop: A crop planted on a trial site after harvest or termination of a confined field trial.

Free-living: A plant living outside cultivation, or surviving without human intervention.

Genetic Engineering/Genetically Engineered (GE): The genetic modification of organisms by recombinant-DNA techniques. For the purposes of this document, the terms '**genetically engineered (GE)**', '**transgenic**', '**genetically modified (GM)**', **genetically modified organism (GMO)',** '**living modified organism (LMO)'** and '**regulated**' are equivalent.

Genetic Modification/Genetically Modified (GM): See 'Genetic Engineering'.

Incident: Any occurrence that causes, or threatens to cause, a breach of confinement of GM plant material.

Material Confinement: Measures taken to ensure that GM plant material is not consumed by

humans, livestock and animals

NBC: The National Biosafety Committee, a committee within UNCST which discharges the responsibilities of UNCST in regulation of GMOs.

Pollen-mediate Gene Flow: The transfer of genes from one plant to another in pollen by successful fertilization.

Principal Investigator: This is the lead scientist in a confined field research study. He may himself be the Authorized Party if he is the applicant or he may be a designated agent or lead scientific collaborator of the Authorized Party.

Prohibited Plants: Plants that are sexually compatible with the GM plants being grown under confinement, and are thus prohibited from the established spatial isolation distance of a confined field trial.

Propagative Plant Material: Plant material such as seeds or cuttings capable of establishing and surviving in the natural environment without human intervention.

Regulatory Authority: The government body having the statutory authority to regulate an activity. For the testing and introduction of GMOs in Uganda, the Regulatory Authority is vested in UNCST (see), and exercised by the NBC (see).

Reproductive Isolation: Measures taken to prevent, principally, pollen-mediated gene flow from plants in the trial site to nearby sexually compatible species. Also known as 'genetic confinement'.

Sexually Compatible: Capable of cross-pollinating and forming viable hybrids without human intervention

Trial Manager: The individual at a particular trial site, designated by the Authorized Party as responsible for management and compliance of an authorized confined field trial. Trial Managers are authorized to complete and sign documentation, forms and notes for the Trial file.

Trial Site: The area of a field trial that is confined by one or more continuous methods of reproductive and/or material isolation

UNCST: The Uganda National Council for Science and Technology, which is the body responsible for regulating the testing and release of GMOs in Uganda.

Volunteers: Progeny arising from the GM crop in a confined field trial site.

1.0 INTRODUCTION

This Handbook provides instructions for all aspects of biosafety for confined field trials in Uganda in form of Standard Operating Procedures (SOPs). The SOPs give detailed instructions for shipping and storage, establishment, maintenance and confinement of Confined Field Trials; termination and post-harvest management of the trial site; and reporting of results to NBC. The forms provided are intended as example formats for collecting typical information required for documentation of compliance requirements. These forms may be customized by the Authorized Party for ease of use in fulfilling specific requirements, as indicated in the Terms and Conditions of authorization for a particular trial. Similarly, the formats suggested for reporting of results may also be modified if needed to meet specific requirements set forth by the NBC for a particular trial.

The procedures provided here are for the use of all Trial Managers, Technical personnel, agents of the Authorized Party, and government officials engaged in planning, conducting or overseeing confined field trials of GM plants in Uganda.

Procedures for the conduct of confined field trials are intended to accomplish three important goals: **1) preventing the escape from the trial site of novel genes in pollen, seed or other plant parts, 2) preventing GM plant material from being consumed by humans and/or animals,** and **3) preventing GM plants from escaping from confinement and establishing and persisting in the environment.** With the achievement of these three goals, novel genes and their products may be confined to the field trial site, and their release into the general environment prevented.

It should be noted that, under Appendix 5 of the National Biosafety Guideline, it is mandatory for the Authorized Party to ensure compliance with the Terms and Conditions of authorization, and that this responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of conducting confined trials. Similarly, the responsibility of the Authorized Party and its employees is not limited to the fulfillment of these procedures in achieving the goals of confinement outlined above; they are required to take all reasonable steps to achieve these goals.

Experience has shown that confined field trials can be conducted safely, with no harm to the environment, humans or animals, by following a systematic approach to their conduct (ref). This approach is based on careful planning, establishment of clear requirements and procedures, on-going education for clear understanding of requirements, effective communication, and careful oversight.

The procedures defined herein apply to all GM materials of any crop undergoing authorized confined field-testing in Uganda. Any requirements listed in the Terms and Conditions of a specific authorization issued by the UNCST shall take precedence over the requirements of these SOPs, if they are found to be in conflict.

2.0 DATA QUALITY AND INTEGRITY

2.1 Introduction

Adequate records are critical to establish the compliance of the Authorized Party with the Terms and Conditions of authorization and other relevant requirements. Clear, authentic and readily accessible records shall be maintained to document critical activities. UNCST therefore publishes the attached example forms, which may be used by the Authorized Party for guidance in developing forms for use in their specific confined trials.

2.2 Instructions for Completing Forms and Documents

2.2.1 Record information directly, promptly and legibly with blue or black pen or electronically. Do not use pencil or whiteout. Capitalize written information.

2.2.2 Date format is Day, Month, Year. Use metric (SI) units such as kg, m, ha for all measurements.

2.2.3 If there is not enough space on a page to record all data or explanations needed, add extra pages and complete the entry there.

2.2.4 Areas left blank for any reason must be lined-out, initialed and dated.

2.2.5 It is acceptable to carry identical information down through a column by use of a line drawn between the first entry and the same entry repeated in the last space of the column.

2.2.6 Changes to entries should be made by drawing one line through the original entry so as not to obscure it, indicate the reason for the change, then initial and date the entry.

2.2.7 Common Correction Codes used to show the reason for a change should be circled, dated and initialed. Common Codes are defined as follows:

Table 1. Common Correction Codes

EE	**= Entry Error**	**ML**	**= Mislocation of Entry**
RC	**= Recalculation**	**ME**	**= Missing Entry**
LE	**= Late Entry**	**NA**	**= Not Applicable**
SP	**= Spelling Error**	**RE**	**= Reevaluation**
EQ	**= Equipment Malfunction**	**WO**	**= Write Over**
CE	**= Communication Error**	**TE**	**= Transcription Error**
CL	**= Clarification**		

2.2.8 The person(s) recording data should date and initial all entries on the day of entry. If multiple entries (by different persons or on different dates) are made on one page, a date and initial are required for each individual entry.

2.2.9 After each page has been completed, it must be signed and dated by the Trial Manager to verify that the information is accurate, legible and complete.

2.2.10 Any additional supplemental records not recorded on the forms provided must be labeled with the description of the trial, and include sufficient explanation for a third party to easily understand the additional documentation.

3.0 STANDARD OPERATING PROCEDURE FOR SHIPPING AND STORAGE

3.1 Packaging and Labeling

3.1.1 Packaging Materials

All GM plant materials for shipping or transport must be packaged in such a fashion to prevent any accidental release. Packaging shall also ensure that tampering can be detected easily. Multiple layers of packaging are required, according to the material being transported. The inner container, usually in direct contact with the GM plant material, is called the 'primary container', and is enclosed within 'secondary' and perhaps 'tertiary' containers. Each layer of packaging must be of such construction and sturdiness to independently prevent the release of the material under normal conditions, and each layer must be independently closeable or sealable. It is advisable, but not required, that at least one layer of packaging be waterproof. Examples of appropriate

packaging are given below:

3.1.1.1 Seeds

Seeds for transport must be contained in three layers of packaging. The inner (primary) container must not allow seeds to become trapped or hidden within, and must be easily verified to be free of all seed. Examples of appropriate primary containers for seeds are: metal cans, plastic bottles, plastic bags. Fibre bags may be appropriate if the mesh size and construction are adequate for the type of seeds being contained. Appropriate secondary containers include: plastic or metal cans or boxes, cardboard or fibreboard boxes or wooden boxes of close-fitted construction. Appropriate tertiary containers include any of the examples of secondary containers listed, as well as wooden boxes or crates. Seed of different experimental units may be separated in sub-containers within the primary container, for example, lines of maize seed in planting envelopes may be placed within a metal can serving as the primary container.

3.1.1.2 Vegetative Material Capable of Propagation

Examples of this category include plantlets for transplanting, 'stakes' for the propagation of cassava, cut potato 'seed pieces', etc. Propagative materials must be contained in two layers of packaging. Examples of appropriate packaging materials are: plastic tubes or pots, metal, cardboard or fibreboard boxes and nylon bags.

3.1.1.3 Material Not Capable of Propagation

Examples of this category include devitalized plant materials and vegetative materials such as leaf samples that cannot propagate. These materials must be contained in two layers of packaging, such as plastic or paper bags or envelopes, wooden, fibre-board or cardboard boxes, etc.

3.1.1.4 Special Case Materials

If large amounts of material are to be transported as the result of a confined field trial, guidance should be sought from NBC on specific packaging requirements appropriate to the material proposed to be transported. For small amounts of material, packaging shall be done as described above.

3.1.2 Labeling

Each layer of required packaging must be labeled with sufficient information to establish the identity of the contents, and the contact details of an official contact person. The label must also contain the following statement or equivalent verbiage: 'Genetically Modified Plant Material For Research Purposes Only. Do Not Use for Food or Feed'. An approved 'Do Not Eat' symbol, found in section 5.4, shall also be included. The Authorization Code Number issued by UNCST shall be included on all packages.

3.1.3 Retention of Packaging

The primary container with its associated labeling is typically used for storage of the GM plant material. All primary containers shall be retained for the duration of the authorization period or until a designated agent of UNCST authorizes their disposal or release.

3.1.4 Disposal or Recycling of Packaging Materials

When disposal or release has been authorized, the primary containers that are in contact with GM plant material shall be cleaned of propagative plant material. The process of cleaning will vary with the type of container and the material being contained. After the packaging has been verified and documented to be free of plant material, it may be disposed of by burying, incineration or by similar means. Outer layers of packaging, that are not in contact with GM plant material, may be returned to general use without restriction, unless a breach of the primary container has occurred, in which case packaging that has come in contact with GM plant material is treated as primary packaging, according to the requirements described herein.

3.2 Shipment and Receipt

3.2.1 Shipping Documentation

A Shipping Form that establishes the identity of the GM plant material and the identity of the originating and receiving parties must accompany all shipments.. The Shipping Form serves as an official record of transport and custody. An example of an appropriate Shipping Form is in the Appendix. Additional inventory lists may be attached to the Shipping Form, if necessary, in order to list all items in a particular shipment. The recipient of the shipment shall retain a copy of the completed Shipping Form, and all other documentation included in the shipment (e.g., Phytosanitary Certificates, Import Permits, etc). Copies of all documentation associated with shipment of GM plant material

shall be copied to UNCST and the Biosafety Inspection Department of the Ministry responsible for Agriculture. The Authorized Party or his agent shall retain original copies of the documentation.

3.2.2 Receipt

Careful verification of receipt is critical to maintaining valid documentation and preventing inadvertent release of GM material. The receiving party shall observe the following requirements upon receipt of shipment:

- Complete the recipient information on the Shipping Form.
- Verify that packaging is intact, and that no release of GM material has occurred. Note any damage to containers in the space provided on the Shipping Form. If any release of GM material is suspected or occurred, notify UNCST immediately, following the procedures defined on the 'Incident Report' Form in SOP 'Incidents'.
- Verify that all items listed on the Shipping Form and any inventory lists have been received. Notify the shipper and/ or carrier immediately to locate any missing packages or items. If a package or item cannot be located, notify UNCST immediately, following the procedures defined on the 'Incident Report' Form.
- Register shipment items into inventory in secure storage as defined below.
- Prepare copies of completed documentation to be retained in the study file at the field trial site.

3.3 Storage

3.3.1 Secure Storage

All GM plant material must be stored and maintained in such a fashion as to preserve its identity, security and integrity, and to prevent it from being consumed by humans, livestock or other animals. To achieve these goals, all GM material shall be stored in a facility or storage area in which:

- Access is restricted to authorized personnel
- The facility or storage area is sign-posted with the information 'GM Plant Material – Not for Use in Food or Feed', or equivalent verbiage
- GM material is kept separate from non-GM materials being stored or maintained in the same facility or area

- GM material is clearly marked or labeled, to prevent misidentification with non-GM materials.

3.3.2 Storage Inventory

A current inventory of all GM materials being stored or maintained in a facility or storage area shall be maintained and available for inspection by designated agents of UNCST.

3.4 Appendices

3.4.1 Approved 'Do Not Eat' Symbol

3.4.2 Example Shipping Form

SHIPPER	**RECEIVER**
Name:	Name:
Title/Organization:	Title/Organization:
Address :	Address:
Phone/Fax:	Phone/Fax:
Email:	Email:

SHIPPING INFORMATION

	Shipped		**Received**	
Item	**Amount**	**By**	**Amount**	**By**
Total				

Packaging description	**Shipper Signature**	
Conveyance	**Conveyor Initial Signature**	
Depart [origin]	**Date**	**Time**
Arrive [destination]	**Date**	**Time**

RECEIVING INFORMATION

Note: Receiver records following information and 'received' columns above.

Received on (date/time):	**Received and checked by (print):**
Title and location of receiver:	
Total [amount] received:	**Phytosanitary permit enclosed? Yes/ No**
Notes on condition upon receipt (damaged containers, etc):	
Storage/transport after receipt:	
Receiver signature:	**Date:**

4.0 STANDARD OPERATING PROCEDURE FOR CONFINEMENT

4.1 Establishing the Trial

4.1.1 Site Security

All sites used for testing of GM plants in Uganda are required to have adequate security, in order to safeguard the GM material and to prevent it from being consumed by humans, livestock and other animals. All sites shall have provisions for limiting access to authorized personnel, and of restricting the site from incursion by livestock or other animals. Proposed sites may be inspected by Biosafety Inspectors of Ministry responsible for Agriculture or other agents of UNCST for compliance with this provision as a condition of trial authorization.

4.1.2 Planting

Planting of GM material must not be done prior to the authorization date given in the official Terms and Conditions of authorization issued by the UNCST. Areas of non-GM plants used for borders, buffers or Border rows may be planted prior to the authorization date, if desired.

4.1.3 Personnel

The Authorized Party shall ensure that all personnel involved with handling the GM plant material from receipt of the shipment through the Field trial to devitalisation are trained on the nature of the material being handled and on the requirements of all relevant SOPs. Where seed or other propagative material is being harvested, an inspection and verification procedure will be implemented to ensure that no such material inadvertently trapped in workers' clothing or bodies is removed from the site.

4.1.4 Equipment

All equipment used to plant a confined field trial shall be cleaned of any propagative GM plant material before being moved from the trial site. Appropriate cleaning methods include manual removal, brushing, compressed air, vacuuming or water. All planting equipment shall be inspected after cleaning and verified to be free of propagative plant material by trial personnel. Disassembly may be required when necessary to verify that the equipment is free of propagative plant material.

4.1.5 Disposal of Excess Material

Any excess planting material, and any propagative material recovered during the cleaning of equipment, shall be recorded and devitalized by heat, incineration, deep burial, chemical treatment, grinding or crushing. Plant material remaining after devitalization shall be disposed of by deep burial. If excess planting material is retained, it shall be packaged, transported and stored in accordance with SOP requirements.

4.1.6 Identification of the Trial Site and Plots

The trial site shall be identified with a sign that gives the Authorization Code Number and the information 'GM plants – For Research Purposes, Not for food or feed. Authorized Personnel Only', or equivalent verbiage. All four corners of the trial site shall be marked with posts suitable to permit identification of the site during the growing season and for the period of post-harvest restriction. Each individual plot of GM plants within the trial site shall have a label establishing the specific identity of the GM plants. A map of the site is required showing the location of the trial site. Requirements for trial site maps and an example of an appropriate map are found in the Figure 1.

4.1.7 Record of Planting

A Record of Planting and a final plot map shall be submitted to NBC within five (5) days after the completion of planting.

4.2 Reproductive Isolation

To prevent the escape of genes in pollen (pollen-mediated gene flow) from the trial site, GM plants shall be isolated from sexually compatible plant species in proximity to the trial site. Sexually compatible plants are called 'prohibited plants', and are described in detail in the Terms and Conditions of authorization of each trial. The techniques used vary with the particular crop species, some of which are described below.

4.2.1 Spatial Isolation

Enforcing a spatial isolation distance is the primary means of assuring reproductive isolation. Isolation distances are derived from observations and experiments of plant breeders, and are described in Table 1. The Trial Manager shall monitor the spatial isolation distance. All prohibited plants shall be removed prior to flowering, otherwise a breach of reproductive isolation shall have occurred.

Table 1: Spatial Isolation Requirements for Common Crops

Plant Species	Minimum Spatial Isolation Distance (m)	Prohibited Plant Species	Monitoring Interval, at least once each (period)
Maize (*Zea mays*)	200	*Zea mays*	1 month
Cassava (*Manihot esculenta*)	100	*Manihot esculenta* Ceara rubber tree (*Manihot glaziovii*)	1 month
Cotton (*Gossypium spp.*)	200	*Gossypium spp.*	1 month
Banana (*Musa spp.*)	Inbreds: 100 Fertile Hybrids: 200	*Ensente, Musa spp*.	Monthly during vegetative growth; bi-weekly after flowering

4.2.2 Early Crop Destruction

Where the objectives of a particular trial may be achieved before the GM plants flower, early crop destruction may be used as a means of reproductive isolation. In this case, the Trial Manager shall document and verify that the GM plants were destroyed prior to any release of pollen.

4.2.3 Removal of Flowers Prior to Pollen Shed

Where male flowers may be readily identified prior to pollen production, as in the case of maize (*Z. mays*,) cassava (*M. esculenta*) and Banana (*Musa sp*.), these flowers may be removed prior to pollen production. Frequent inspection, as specified in Table 2, is required to ensure that all male flowers are removed, thus verifying that no pollen was shed.

4.2.4 Prevention of Viable Pollen Production or Release

The production of viable pollen may be prevented through genetic means such as male sterility, or the release of pollen may be prevented by physical means such as the bagging of male flowers (tassels) in maize. Where these techniques are proposed as the primary means of reproductive isolation for a confined field trial, the Applicant is required to submit justification and detailed methodology to support the proposal.

Table 2: Alternative Methods of Reproductive Isolation

Crop	Method	Requirements
Banana	Bagging and Removal of Male Bud	Bag flower and remove male bud as soon as the distal female bracts curl to expose last formed fingers. Border rows of 3 m (1 row) are required.
Cassava	Border rows	3 m (3 rows) width required. Inspect weekly for integrity and flowering characteristics during the period of flowering of the GM plants.
Cassava	Removal of Flowers	Inspect weekly during flowering period, remove at flower bud stage before flowers open
Cotton	Border rows	12 m width required. Inspect weekly for integrity and flowering characteristics during the period of flowering of the GM plants.
Maize	Bagging of Tassels	Inspect daily during flowering period, bag tassels at emergence prior to pollen shed
Maize	Removal of Male Flowers ('detasseling')	Inspect daily during flowering period, remove tassels before fully emerged, prior to pollen shed.

4.2.5 Border rows

Establishment of Border rows (pollen-trap rows) is appropriate in crops that are insect-pollinated, such as cotton (*G. hirsutum*) and cassava (*M. esculenta*). The Border rows attract pollinating insects, thus limiting the spread of GM pollen (USDA-APHIS, 2000; Berkey et al., 2002; Llewellyn and Fitt, 1996).

To be effective, plants in the Border rows must flower at the same time as the GM plants and be of approximately the same growth habit and stature. The simplest way to achieve this is to use plants of the same or very similar non-modified genotype as the GM plants, planted at the same time and in the same fashion. Border rows must completely surround the GM trial site on all sides, and must not have any continuous gap (alley way or pathway) transversing the Border rows. The Trial Manager shall document that the Border rows are intact and that the GM plants and Border rows have a similar flowering period and growth habit.

When Border rows are used for genetic isolation, the exterior of the plot, measured from the outside of the Border rows, shall be a minimum distance from any prohibited plants

as a secondary mechanism of reproductive isolation. The entire area including the Border rows shall be considered to be the 'plot area' for purposes of post-harvest restriction and volunteer monitoring.

To ensure that the highest degree of confinement is attained, the **minimum isolation distance is always required**, regardless of any additional alternative methods of reproductive isolation.

4.2.6 Breach of Reproductive Isolation

Breach of reproductive isolation is an extremely serious incident, and shall be reported to UNCST according to instructions found herein. The Authorized Party may be required by NBC to destroy the field trial or any prohibited plants within the spatial isolation distance immediately. The Authorized Party shall be responsible for any legal or financial consequences resulting from breach of reproductive isolation. Remedies for specific instances of breach of reproductive isolation are described below.

4.2.7 Breach of Spatial Isolation Distance

Where prohibited plants are allowed to flower within the spatial isolation distance, these plants must be destroyed. In this case, the post-harvest restriction and monitoring requirements may be made more stringent and the period of post-harvest monitoring may be extended, at the discretion of NBC.

4.2.8 Breach of Alternative Methods of Reproductive Isolation

Where any alternative method of reproductive isolation mentioned here has occurred, the minimum spatial isolation distance becomes the default method of reproductive isolation, and the Authorized Party shall be required to enforce such isolation distance and shall be responsible for any legal and financial obligations that may be incurred.

4.3 Monitoring the Trial

All confined field trial sites shall be monitored by trial personnel and Biosafety Inspectors, in order to ensure reproductive isolation and material confinement, and to gather data on the characteristics of the GM plants being tested. Additional data beyond that described in this Section may be required by the NBC, and these requirements shall be incorporated in the Terms and Conditions of authorization.

4.3.1 Isolation

The minimum spatial isolation distance shall be inspected by the Trial Manager for prohibited plants at least monthly from planting until harvest of the confined trial. All prohibited plants must be destroyed before they flower. The process of inspection, identification and destruction of prohibited plants will be recorded and verified by trial personnel.

Where alternative methods of reproductive isolation are authorized, monitoring requirements vary with the crop and method employed. Monitoring Intervals for some crops are suggested in Table 1.

4.3.2 Plant Growth and Development

The growth and development of GM plants shall be monitored regularly from planting until harvest of the confined trial. Any unanticipated effects on growth and development of the GM plants, compared to non-modified control plants, shall be reported to NBC.

4.3.3 Target Effects/Efficacy of the GM Plants

The Authorized Party shall design a monitoring program adequate to establish the efficacy of the genetic modification(s) in the trial. Any unanticipated target effects of the genetically engineered plants, compared to non-GM control plants, shall be recorded and reported to UNCST.

4.3.4 Non-Target Effects o the GM Plants

Monitoring for specific non-target effects may be required, depending on the crop and genetic modification in the trial. The Authorized Party may suggest a monitoring program for non-target pests, diseases or for environmental impacts, including details in the Application for Confined Field Trial, or elements of non-target monitoring may be required as a condition of authorization by the UNCST. Any unanticipated effects of the genetically modified plants on non-target species, compared to non-modified control plants, shall be recorded and reported to UNCST.

4.3.5 Post-Harvest Monitoring

Post-harvest monitoring and reporting is required for all confined field trial sites.

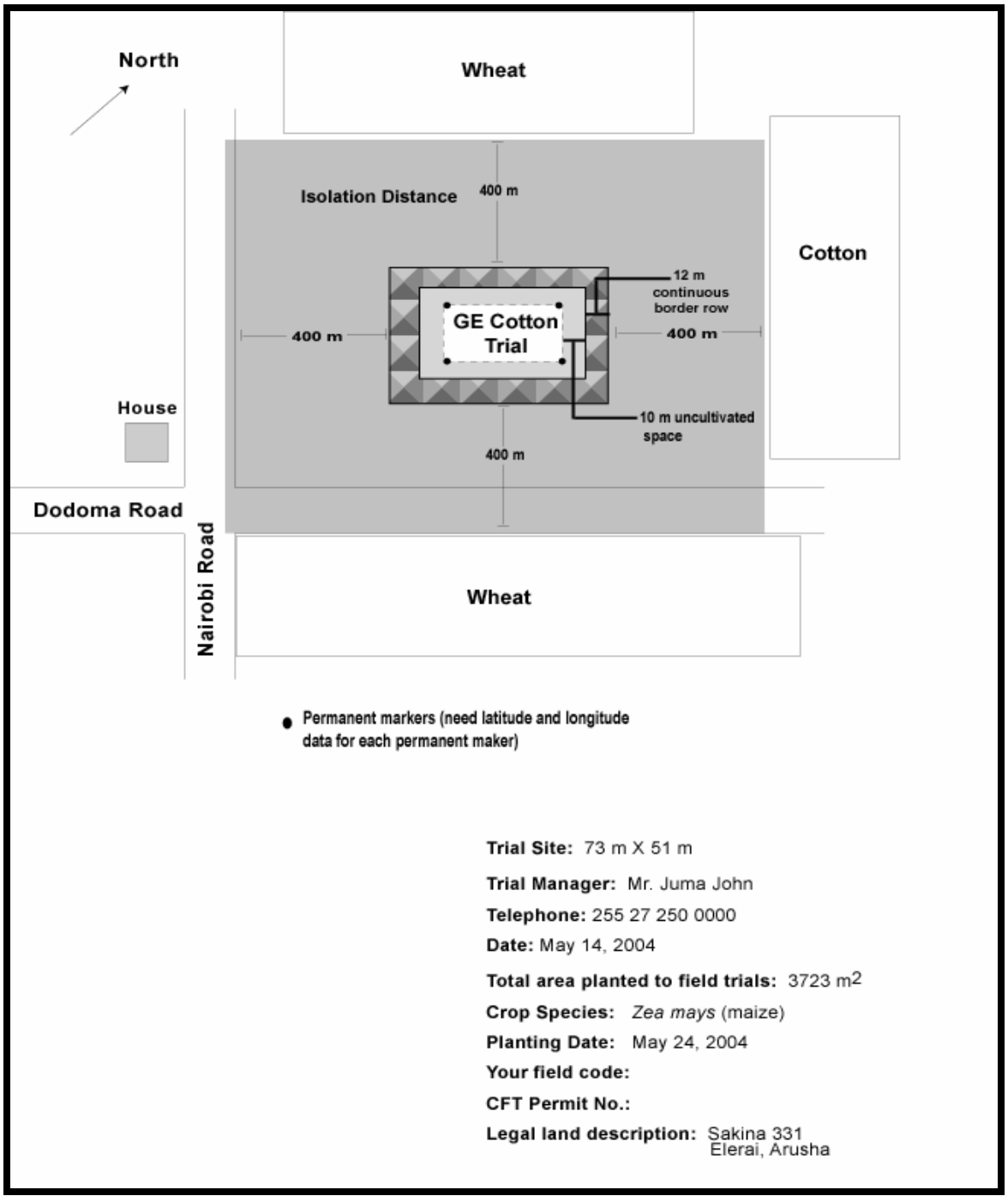
4.4 Appendices

4.4.1 Preparation of Trial Site Maps

A preliminary map of the confined field trial site shall be submitted with the application, and a final field map is required with the Planting Report submitted within five (5) days after completion of planting at each site. All maps shall be legible and precise, drawn on plain paper with crisp line drawings and block letters. Maps on lined or graph paper, or photocopies of road or topographical maps will not be accepted. The following information must be included on each map:

- The general location of the field trial (District/sub-county/station).
- Compass directions, with North at the top of the page.
- Location of the trial site in relationship to permanent landmarks such as roads, buildings or fences. GPS coordinates of the site may be provided, if available. The location of the trial site must be recorded with enough precision that current year and post-harvest monitoring and inspection may be accomplished.
- Exact trial dimensions shall be noted on final field maps.
- Surrounding crops within the spatial isolation distance shall be indicated.
- If the area of a previous trial is still under post-harvest restriction at the same site, the restricted area should be indicated.
- The name and phone number of the trial manager or field contact shall be given.
- For final field maps, the authorization code number and planting date of the trial shall be included.

Figure 1: Example of Properly Prepared Map with One Trial at a Single Trial Site



4.4.2 Example Forms

PLANTING OF CONFINED TRIAL			
Trial:		**Site:**	
Authorization Code Number:		**Planting Date:**	
Instructions: Record the information requested below. Use additional pages if needed to record any notes or details. Excess planting material should be stored or disposed of by [approved method], or according to specific instructions.			
Line Number	**Amount Planted**	**Amount Retained**	
Comments on Planting:			
Intended Purpose of Retained Plant Material:			
Storage Location:		Storage Location Secure: Yes No	
Comments on why store:			
Shipping Containers Sterilized/Inspected/Destroyed by (Circle All That Apply): Bleach Solution / Burned / Other (describe)			
Treated/Disposed of by (Initials)		Date	
Total Genetically Modified Planted	Seed	Plots	Ha
Total Area, Including Non-GM Plants and Plots	Length (m)	Width (m)	Ha
Reminder: Include a verified, signed and dated plot map in the study file. Plant [approved borders] according to the approved plot diagram. Complete and submit Planting Report with final plot map within five (5) days of completing planting.			
Checked for Accuracy and Completeness by Trial Manager **Signature:** **Date:**			

ISOLATION MONITORING

Trial:	**Site:**
Authorization Code Number:	

Instructions: Inspect [distance] surrounding the trial site each [interval], starting at planting. Identify and destroy any prohibited plants – [list] -- within the [distance] isolation area. Continue monitoring until the GM plant material in the trial site is destroyed.

Inspection Date (Day/Month/Year)	**Prohibited Plants Present? What Growth Stage and location?**	**Prohibited Plants Destroyed? By What Method?**	**Comments**	**Verified By (Initials)**
EXAMPLE: ***14 July 2005***	***Yes–2 seedlings***	***Yes-hoe***	***None***	***SM***

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

PERIOD PLOT OBSERVATIONS

Trial: **Site:**

Authorization Code Number:

Evaluated By: **Date:**

Plot	Rep	Line	Insects (Scale)		Diseases (Scale)			Hgt (cm)	Comments/ Other Observations
1	1								
2	1								
3	1								
4	1								
5	1								
6	1								
7	2								
8	2								
9	2								
10	2								
11	2								
12	2								
13	3								
14	3								
15	3								
16	3								
17	3								
18	3								
19	4								
20	4								
Line Avg:									

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

FLOWER BUD REMOVAL WEEKLY REPORT

Trial: **Site:**

Authorization Code Number:

Instructions: Summarize results of flower bud removal each [time], starting [time] after planting in soil, or earlier if branching is observed. Dispose of all flower buds by [method]. Answer Y/N except as indicated.

Week of (Dates)	Number of Inspections This Interim	Flower Buds Present?	All Flower Buds Removed Prior to Pollen Production?	Flower Buds Disposed of in On-Site Disposal Pit?	Verified By (Initials)

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

PHONE AND COMMUNICATION LOG

Trial:	**Site:**
Authorization Code Number:	

Instructions: Keep a copy of this form at your desk. Record all phone conversations, and all relevant personal communications. When the log is full, file and obtain a new blank copy.

Spoke With	Date/Time	Mode*	Summary	Initials

Ph = phone; Con = conversation ; F = fax communication ; E = email. Note 'To' or 'From'.

5.0 STANDARD OPERATING PROCEDURES FOR SAMPLING

5.1 Introduction

One objective of a confined field trial may be to obtain samples of different plant tissues, in order to identify genetic elements, determine levels of expression of proteins or other plant constituents, or to establish composition of the plant tissues. Types of samples and the tissues to be sampled vary widely, depending on the specific objectives of the trial. Specific sampling requirements and methodologies are typically established in the Study Plan.

In all cases, however, fundamental principles of sample cleanliness, sample identification and sample integrity generally apply. These fundamental principles are outlined in this Procedure.

5.2 Avoid Contamination

To obtain samples and resulting data that are scientifically valid and useful, it is critically important to avoid mixing of even the smallest amount of tissues between different samples, an occurrence called 'cross-contamination'. This is achieved by strictly following these simple measures:

- Wear clean disposable gloves when sampling, and change them after each plot or entry is sampled;
- Wash thoroughly all sampling tools and rinse them with clean solvent (e.g., clean water) between sampling different plots or entries;
- Do not contaminate samples with chemicals, dirt or soil. Use a clean plastic drop cloth or other clean surface to place samples on, if necessary;
- Follow instructions in the Study Plan to determine the order in which samples are taken. Typically, the non-GM control will be sampled first, followed by the GM entries, but this may vary depending on the plant materials and objectives of the trial.
- Always use new sample bags as the primary container for the samples, i.e., the container directly in contact with the sample itself. Securely close each container after placing the sample inside.
- Place control samples in a separate secondary and tertiary containers from the GM samples. If separate secondary containers are not available, samples may be double contained and physically separated.

5.3 GM Tissue Sample Collection

Collect the type and amount of tissue required by the Study Plan. An inexpensive scale such as a bathroom scale may be used to determine approximate amounts in the field. Do not wash, strip, brush or trim the samples unless these steps are specified in the Study Plan.

Unless otherwise specified by the Study Plan, all samples should be placed on dry ice or in a freezer within 30 minutes of collection, and should be maintained at or below freezing during processing and shipment.

5.4 Sample Identification

Follow instructions in the Study Plan for sample identification or coding. Completely fill out all required information on the sample bag prior to or at the time of sampling. Always use a permanent marker pen if sample information is recorded directly on the sample bag. All samples shall be labeled uniquely, and in a fashion that cannot be lost, obscured or obliterated. The date of collection of each sample shall also be recorded on the sample bag or primary container.

5.5 Sample Storage

Follow instructions in the Study Plan for sample storage. Typically, samples are required to be frozen soon after collection, and to be maintained in a frozen state.

5.5.1 Equipment Requirements

If specified by the Study Plan, samples may be maintained on dry ice for several days, if no freezers are available. The amount of dry ice should be monitored at least twice a day, and more dry ice added as needed. Monitoring and addition of ice shall be documented.

If freezers are available, these should be capable of maintaining an average temperature within the range acceptable for sample storage, and this capability shall be verified before use with an appropriate temperature monitoring device such as a minimum/maximum thermometer for a period of at least three (3) days. The temperature range recorded should be within +/- 3ºC for the monitoring period.

If multiple freezers for the storage of control and GM samples are not available, these samples should be stored in separate parts of the freezer, e.g., on separate shelves.

Freezers should be located in a clean and secure area away from direct sunlight. Electrical outlets used should be grounded and the Trial Manager shall verify that the circuits used are not overloaded. The outlet should not be connected to a wall switch that could accidentally be turned off, and the cord and plug should be secured or protected so that the plug cannot be inadvertently pulled from the outlet. There should be unobstructed airflow around the coils and adequate space within the freezer to maintain the integrity of the samples.

A sample storage log shall be maintained for all samples in storage. This log shall record the following information: Trial Site Identification, a brief description of the samples stored or sample identification, date and person storing the samples, date and person shipping the samples.

5.5.2 Equipment Monitoring

Equipment used for sample storage should be monitored by use of a recording device such as a minimum/maximum thermometer. A temperature log shall be maintained recording the minimum, maximum and current temperature, as well as the date and initials of the recorder, at least weekly while samples are being stored. A suggested contingency to verify that constant freezing temperature has been maintained is to invert a small container such as a test tube with frozen water in the bottom into a larger container such as a beaker. If the temperature rises above freezing for an appreciable amount of time, the ice will fall out of the small container. The samples should then be checked for defrosting, and this occurrence noted in the study file.

5.5.3 Equipment Failure

In case a freezer fails due to power outage or malfunction, limit the number of times that the freezer is opened, to retain cold in the freezer. If the failure lasts longer the 24 hours, or the temperature exceeds 0ºC for more than a few minutes, place dry ice in the freezer to maintain the samples in frozen condition.

5.6 Sample Packaging and Shipment

Sample packaging and shipment shall conform to requirements established by the UNCST appropriate to sample type, and to relevant SOP requirements. Typically, samples of non-propagative tissues, e.g., leaf samples taken for laboratory analysis, require no special packaging or labeling.

Special steps may be required to maintain sample integrity of delicate tissue samples

during shipment, such as the inclusion of dry ice.

The following procedures are generally appropriate, depending on objectives or sample types:

- Samples should be shipped in new boxes or containers;
- If possible, control and GM samples should be shipped in separate containers;
- When shipments have multiple containers, the containers should be numbered sequentially, and the total number of containers indicated on the Shipping Form;
- A manifest listing all samples in the shipment should be included in 'Box #1' of the shipment. Write 'packing slip enclosed' on the appropriate container;
- Dry ice may be required to maintain the samples in the frozen state, in which case a minimum of approximately 5 to 10 kg of dry ice per 1 kg of packaged sample (weight of sample plus associated packaging) is appropriate, distributed equally above and below the samples. Alternatively, shipping by specialized carrier such as a freezer truck may be required. Where samples are to be shipped frozen, close coordination with the receiver is advisable, to ensure sample integrity during shipment and receipt. Document all communication with the Authorized Party and/or sample recipient on an appropriate Communication Form. Consult the Study Plan for specific recommendations and requirements according to Trial and sample type.

6.0 STANDARD OPERATING PROCEDURE FOR TERMINATION

6.1 General Requirements

6.1.1 Trial Termination

The requirements of this SOP apply equally to trials undergoing normal harvest, and those that are terminated prior to normal harvest. The term 'harvest' is construed herein to include early termination of a trial, as applicable. If a trial has been terminated prior to flowering as a measure of reproductive isolation, the post harvest restriction may be waived upon written approval by UNCST.

6.1.2 Consumption and Persistence

Two of the overarching goals in the conduct of any confined field trial are: 1) preventing consumption of GM plant material by humans or livestock and other animals, and 2) preventing GM plants from establishing and persisting in the environment. The Authorized Party, Trial Managers and all trial personnel are required to take all

reasonable steps to ensure that these goals are accomplished, including, but not limited to, compliance with the procedures described herein.

6.1.3 Notification of Intent to Harvest

The Authorized Party shall notify UNCST at least five (5) working days prior to the intended date of harvest, in order that an Inspector may be present during harvest. The presence of an Inspector is at the discretion of UNCST, and is not a requirement of this SOP.

6.1.4 Personnel

All personnel involved in harvest activities will be instructed by the Trial Manager on the nature of the material being harvested and on the requirements of this SOP. Where seed or other propagative material is being harvested, an inspection and verification procedure will be implemented to ensure that no such material inadvertently trapped in workers clothing is removed from the site.

6.1.5 Equipment

All equipment used to harvest a confined field trial shall be cleaned of plant material before being moved from the trial site. Appropriate cleaning methods include manual removal of seed or plant parts, brushing, compressed air, vacuuming or water. All harvest equipment shall be inspected after cleaning and verified to be free of plant material by trial personnel. Disassembly may be required to verify that the equipment is free of plant material.

6.1.6 Border Rows

In cases where border rows have been used as a measure of reproductive isolation, plant material in the border rows is assumed to be GM, and is subject to all requirements for devitalization and disposal described in this SOP.

6.1.7 Disposal Site

GM plant material shall be disposed of at the confined field trial site, unless off-site movement has been authorized by UNCST.

6.1.8 Retention of Material

If any plant material is to be retained from the trial for research purposes, the details of this activity shall be specifically authorized by UNCST.

6.1.9 Packaging, Transport and Storage

Any GM plant material authorized for off-site movement is subject to the requirements of the Shipping and Storage SOP.

6.1.10 Incident and Corrective Action

Any incidents of inadvertent release arising from harvest activities are subject to the reporting requirements as described in the Incidents SOP.

6.2 Devitalization and Disposal

6.2.1 Devitalization and disposal

Plant material may be devitalized and disposed by heat, incineration, deep burial, chemical treatment, grinding or crushing, or by cultivation into the soil. Where deep burial is used, the depth must be sufficient to prevent accidental exposure of the material or the emergence of living plants. In most cases, a depth of 1 m of soil covering the top of the plant material is sufficient to achieve these goals. Herbicides for devitalization shall be applied according to labeled use instructions for Uganda, according to the Control of Agricultural Chemicals Statute (1989), unless specifically authorized by UNCST.

6.2.2 Post-Harvest Monitoring

Confined field trial sites are subject to post-harvest restriction and monitoring as described in SOPs for Post-Harvest Management. Where plant material is devitalized or disposed of by burial or by cultivation into the soil, the disposal areas are also subject to post-harvest monitoring.

6.3 Records and Reports

Details of harvest and disposal shall be recorded by trial personnel on appropriate forms, see the Appendix for an example. The Authorized Party shall submit a Harvest Report within five (5) working days after the completion of harvest.

6.4 Appendix

6.4.1 Example Harvest and Crop Destruction Form

HARVEST AND CROP DESTRUCTION FORM			
Trial:		**Site:**	
Authorization Code Number:			
Instructions: Record the information requested below. Use additional pages if needed to record any notes or details. Harvested material must be disposed of by [authorized method] after final harvest yields are obtained.			
Describe Harvest Method and Equipment Used:			
Harvest Date	**Equipment Cleaned On-Site (Y/N)**	**All Viable Plant Material Retained On-Site (Y/N)**	**Verified By (Initials):**
Describe Procedure for Destruction of Plant Materials, Including Dates:			
Notes or Comments on Harvest and Destruction of Crop Material:			
Reminder: Permit Terms and Conditions [do/do not] allow any plant material from the trial to be retained on-site. [All/excess] material must be disposed of by [authorized method].			
Checked for Accuracy and Completeness by Trial Manager **Signature:** **Date:** **Inspector's Name and Signature** **Date:**			

7.0 STANDARD OPERATING PROCEDURE FOR POST-HARVEST MANAGEMENT

7.1 Procedures

7.1.1 Post-Harvest Restriction

All confined field trial sites with GM plants in Uganda are subject to post-harvest restriction and post-harvest monitoring. These requirements allow volunteers of the GM plants to be identified and destroyed, so that:

- Humans, livestock or other animals do not consume the GM plant material.
- GM plants cannot outcross with plants outside the trial site.
- GM plants cannot persist in the environment.

7.1.2 What is Restricted

No plants may be grown on the trial site that would interfere with the identification and destruction of volunteers from the GM trial. This restriction typically includes the crop species itself, and any other plants that are similar in morphology and/or growth habit. If volunteers are to be controlled by herbicide application, it is preferable that the following crop not be sensitive to the proposed herbicide. Table 4 shows crops that are typically acceptable for use following different GM crops.

A GM trial of the same crop as grown in the previous confined field trial is usually acceptable, when grown under specific Terms and Conditions of authorization issued by the UNCST.

The post-harvest restriction may be waived upon approval of UNCST, if the GM plants in the trial site were not allowed to set seed, and this has been verified by the Authorized Party.

Table 3: Post-Harvest Requirements for Common Crops

Plant Species	Examples of Appropriate Following Crops	Post-Harvest Period (years)	Monitoring Interval, at least once each (months)
Maize (Zea mays)	Short Stature Dicots (e.g., squash, melon, vegetables)	1	1
Cassava (Manihot esculenta)	Maize or other grain	1	3
Cotton (Gossypium hirsutum)	Maize or other grain	1	1
Banana (Musa spp.)	Maize, cotton, short stature dicots	1	3

7.1.3 Post-Harvest Period

The post-harvest restriction and monitoring begins at harvest or termination of the trial, and continues for the duration of the post-harvest period. The post-harvest period is designed to extend beyond the time when the seed bank of GM plants in the soil is depleted, and the trial site may be returned to unrestricted usage. Post-harvest periods for common crops are shown in Table 3. The post-harvest period may be terminated earlier than the full time shown in the Table, upon approval of UNCST, if no volunteers are noted for three (3) monitoring intervals favorable for crop germination and growth.

7.1.4 Post-Harvest Monitoring

Trial personnel shall monitor the trial site at the intervals shown in Table 3, recording the presence and growth stage of volunteers, and the method of their destruction.

7.1.5 Border Rows

In cases where border rows have been used as a measure of reproductive isolation, the area of the border rows is considered to be part of the trial site, and is subject to all requirements described in this SOP.

7.1.6 Breach of Spatial Isolation during the Season

Where there has been an established breach of spatial reproductive isolation distance during the season -- where prohibited plants have been allowed to flower within the spatial isolation distance -- the spatial isolation distance shall also be subject to post-harvest restriction and monitoring requirements described in this SOP.

7.1.7 Destruction of Volunteers

Volunteers shall be destroyed before flowering, and shall be disposed of within the trial site in a fashion that prevents consumption by humans, livestock or other animals. Appropriate methods of destruction include chemical treatment or cultivation into the soil. Herbicides for devitalization shall be applied according to labeled use instructions according to the Control of Agricultural Chemicals Statute (1989), unless specifically authorized by UNCST. If volunteers are allowed to flower within the trial site, this constitutes a serious breach of compliance.

7.1.8 Equipment

All equipment used to destroy volunteers on a confined field trial site shall be cleaned of plant material before being moved from the trial site. Appropriate cleaning methods include manual removal of plant material, brushing, compressed air, vacuuming or water. All such equipment shall be inspected after cleaning and verified to be free of plant material by trial personnel.

7.1.9 Non-Compliance

Where there has been an established breach of compliance with these requirements, the post-harvest restriction shall be extended for an additional post-harvest monitoring period. If prohibited plants are present in the spatial isolation distance at the time of flowering of the volunteers, and there is a possibility that they may have cross-pollinated with the volunteers, then the post-harvest restriction shall extend to the spatial isolation distance required for the GM plants. The Authorized Party shall be responsible for any legal or financial obligations incurred due to any incident of non-compliance.

7.2 Records and Reports

Details of post-harvest management of the trial site, including monitoring and destruction of volunteers and establishment of any following crop shall be recorded by trial personnel. An example of an appropriate Volunteer Monitoring Form may be found in the Appendix. The Authorized Party shall submit a Final Report within six (6) months after the completion of the post-harvest period.

7.3 Appendices

7.3.1 Example Volunteer Monitoring Form

VOLUNTEER MONITORING				
Trial:			**Site:**	
Authorization Code Number:				
Instructions: Inspect the trial site for volunteers each [time period], starting one month after harvest. Identify and destroy any volunteer [crop] and note the method. Continue monitoring until the end of the post-harvest interval, xxx months after harvest.				
Inspection Date (Day/Month/Year)	**Volunteers Present?**	**If Present, What Growth Stage?**	**Volunteers Destroyed? Method of Destruction.**	**Verified By (Initials)**
EXAMPLE: 14 July 2006	***Yes***	***Seedlings***	***Yes – Cultivation***	***SM***
Checked for Accuracy and Completeness by Trial Manager				
Name and Signature:			**Date:**	

8.0 STANDARD OPERATING PROCEDURES FOR INCIDENTS

8.1 Principle Goals

Procedures for the conduct of confined field trials are intended to accomplish three important goals: 1) preventing the escape from the trial site of novel genes in pollen, seed or other plant parts, 2) preventing GM plant material from being consumed by humans, livestock or other animal, and 3) preventing GM plants from establishing and persisting in the environment. With the achievement of these three goals, novel genes and their products may be confined to the field trial site, and their release into the general environment prevented.

The Terms and Conditions of authorization of each specific confined field trial, and the SOPs and Guidance Documents published by UNCST, are intended to assist the Authorized Party in achieving the three goals. It is mandatory for the Authorized Party to ensure compliance with the applicable guidance associated with the confined trial and the handling of GM plant material. This responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of establishing and maintaining the trial site or handling the GM plant material. The Authorized Party is required to take all reasonable steps to ensure that these three goals are accomplished, including, but not limited to, compliance with all Terms and Conditions and relevant guidance given by UNCST.

8.2 Infractions

Serious compliance infractions or incidents involve direct violation of the three principle goals, for example: planting without authorization, accidental or unauthorized release of GM plant material, consumption of GM plant material by humans, livestock or other animal, or failure to monitor and destroy volunteers. For such serious incidents, or for gross negligence of compliance requirements, substantial fines may be imposed by UNCST for each instance.

8.3 Notification

Where an accidental or unauthorized release of GM plant material has occurred or is suspected, UNCST shall be notified orally immediately and in writing within 24 hours of the incident. An example of an appropriate Incident Reporting form may be found in the Appendix. All notifications or reports shall be submitted to:

NBC Secretariat
Uganda National Council for Science and Technology
P.O. Box 6884, Kampala, Uganda
Telephone: 256-41-250499
Facsimile: 256-41-234579
Email: uncst@uncst.go.ug
Website: http://www.uncst.go.ug

8.4 Corrective Actions

8.4.1 Unauthorized or Accidental Release

Where unauthorized or accidental release of GM plant material has occurred or is suspected, the following steps should be taken:

1. ***Stabilize the situation.*** Prevent any escape and establishment and persistence in the environment.
2. ***Prevent consumption.*** Prevent material from being eaten by humans or animal.
3. ***Recover the material*****.** Recover all material possible.
4. ***Notify UNCST*****.** Notify UNCST and follow any instructions given.
5. ***Mark or record the exact location*****.** Mark or record the exact location, in case follow up monitoring is required.
6. ***Dispose of material*****.** If necessary, dispose of any GM plant material in an appropriate fashion.
7. ***Follow up monitoring or detection*****.** Follow up monitoring may be required at the discretion of NBC.

8.4.2 Other Incidents

In the case of other incidents or serious compliance infractions, notify UNCST as described above, and follow any instructions given.

8.5 Contingency Planning

Good contingency planning for serious incidents, however unlikely, is the key to successful amelioration of any exposure or environmental impact from these incidents. The Authorized Party shall establish a contingency plan in accordance with the requirements of this SOP, and shall train all trial personnel on this SOP or other authorized contingency plan.

8.6 Appendices

8.6.1 Example Incident and Corrective Action Reporting Form

INCIDENT AND CORRECTIVE ACTION	
Trial:	**Site:**
Authorization Code Number:	
In case of any breach of confinement, follow these steps: ***1. Stabilize the situation.*** ***2. If material is released, recover all material possible.*** ***3. Take all actions necessary to prevent material entering food and feed. Mark the site of release.*** ***4. In the case of accidental release, inform AP management and UNCST immediately by phone.*** ***5. Complete and fax incident report within 24 hours. Contact numbers are given below.***	
AP Manager **Phone (O):** **Phone ©:** **Fax:**	**UNCST** **Phone (O):** **Phone ©:** **Fax:**
Describe the Breach of Confinement, Including Personnel Involved and Corrective Actions Taken:	

COMMUNICATION LOG

Number or Person Contacted	Date/Time	Mode*	Summary of Communication and Agreed Actions	Initials

Ph = phone; Con = conversation ; F = fax communication ; E = email. Note 'To' or 'From'.

Summarize Current situation and Corrective Actions Taken or Agreed Upon:

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

9.0 STANDARD OPERATING PROCEDURE FOR REPORTING

9.1 How to Report

Forms shall assist in the reporting. All reports shall be submitted by regular mail, courier, facsimile, or electronically to:

NBC Secretariat
Uganda National Council for Science and Technology
P.O. Box 6884, Kampala, Uganda
Telephone: 256-41-250499
Facsimile: 256-41-234579
Email: uncst@uncst.go.ug
Website: http://www.uncst.go.ug

Reports required are described in the sections below. All reports shall reference the Authorization Code Number assigned to the trial.

9.2 In-Season Reports

The following reports are required during the conduct of the trial.

9.2.1 Trial Establishment Report

The Authorized Party shall submit details of site establishment within five (5) working days after the completion of planting at the site. The report will include the planting date, the amount of material planted, disposal and storage of any surplus GM plant material remaining after planting, and the size of the trial site. A final field site map shall also be submitted at this time.

9.2.2 Trial Progress Report

The Authorized Party shall submit a progress report after completion of the flowering period of the crop. The report will include flowering information and results of activities enforcing reproductive isolation.

9.2.3 Harvest Report

The Authorized Party shall submit details of site harvest within five (5) working days after the completion of harvest at the site. The report will include the date and method of harvest, the storage or disposal of any harvested materials, and the method of destruction of any residual plant material on the site.

9.3 Other Reports

The following reports are required in the unusual circumstances described below.

9.3.1 Incident and Corrective Action Report

The Authorized Party shall orally notify UNCST immediately, and in writing within 24 hours, of any incident involving an accidental or unauthorized release of genetically engineered plant material. The report will include any corrective actions taken or planned to contain GM material and ameliorate the incident.

9.3.2 Unanticipated Effects Report

The Authorized Party shall notify UNCST in writing within five (5) working days if the GM plants exhibit any substantial unanticipated characteristics or effects, or if any unusual event occurs that may jeopardize the confinement of the GM plants.

9.4 Final Reporting

The following summary reports are required for each confined field trial.

9.4.1 Interim Report

The Authorized Party shall submit an Interim Report within six (6) months after the harvest or termination of the trial summarizing observations, methods of observation, data and analysis of experimental results concerning the trial, required observations, and any unanticipated effects.

9.4.2 Final Report

The Authorized Party shall submit a Final Report within six (6) months after the completion of the post-harvest period summarizing observations on volunteers and their destruction.

9.5 Appendix

9.5.1 Example Report Formats

PLANTING REPORT FOR CONFINED FIELD TRIAL		
Trial Site:	**Location:**	
Permit Number(s):	**Authorized Party:**	
Trial Manager:	**Phone/Fax:**	
Trial Approval Date:	**Planting Date(s):**	
PLANTING		
Total genetically modified planted:		ha (required)
		Plants (optional)
		Plots (optional)
Total area planted, including borders:		ha
Comments:		
DISPOSITION OF PLANTING MATERIAL		
Unless otherwise noted, check Yes or No in the appropriate box.	**YES**	**NO**
Was excess GM planting material destroyed?		
If yes, how?		
Was any GM planting material retained?		
If yes, where is it being stored?		
If yes, what amount was retained?		
Were there any significant occurrences during planting that may have affected confinement of the GM material?		
If yes, describe:		
Comments:		
Trial Manager Signature:	**Date:**	
Date Submitted:		
REQUIRED ATTACHMENTS ▪ **Final Field Map** ▪ **Completed 'Planting of Confined Trial' Form**		

TRIAL PROGRESS REPORT FOR CONFINED FIELD TRIAL	
Trial Site:	**Location:**
Permit Number(s):	**Authorized Party:**
Trial Manager:	**Phone/Fax:**
Planting Date(s):	
Date Flowering Began:	**Date Flowering Ended:**

REPRODUCTIVE ISOLATION AND CONFINEMENT

List measures taken to assure reproductive isolation and confinement:

Comments:

Unless otherwise noted, check Yes or No in the appropriate box.	**YES**	**NO**
Were all measures for reproductive isolation carried out according to requirements?		
If no, describe:		
Was any breach of reproductive isolation noted during flowering?		
If yes, describe:		
If yes, was an Incident Report filed?		

Comments:

Inspector Signature:	**Date:**
Date Submitted:	

HARVEST REPORT FOR CONFINED FIELD TRIAL			
Trial Site:	**Location:**		
Permit Number(s):	**Authorized Party:**		
Trial Manager:	**Phone/Fax:**		
Planting Date(s):	**Harvest Date:**		
HARVEST RESULTS			
Unless otherwise noted, check Yes or No in the appropriate box.		**YES**	**NO**
Method of harvest:			
Was any harvested GM material disposed of?			
If yes, how?			
Was any harvested GM material retained?			
If yes, where?			
Amount:			
Method of destruction of residual plant material on the site:			
Were there any significant occurrences during harvesting that may have affected confinement of the GM material?			
If yes, describe:			
Comments:			
Inspector present? Yes/No			
Trial Manager Signature:	**Date:**		
Date Submitted:			
REQUIRED ATTACHMENTS ▪ **Completed 'Harvest and Destruction' Form**			

INCIDENT AND CORRECTIVE ACTION REPORT	
Trial Site:	**Location:**
Permit Numbers:	**Authorized Party:**
Trial Manager:	**Phone/Fax:**
Attach a completed Incident and Corrective Action form to this cover sheet. Use the space provided below if needed to summarize details of the incident, corrective actions, follow-up actions in-progress or planned, or current status.	
Trial Manager Signature:	**Date:**
Date Submitted:	
REQUIRED ATTACHMENTS ▪ **Completed 'Incident and Corrective Action' Form**	

UNANTICIPATED EFFECTS REPORT			
Trial Site:		**Location:**	
Permit Numbers:		**Authorized Party:**	
Trial Manager:		**Phone/Fax:**	
Planting Date(s):			
Describe any substantial unanticipated or unusual effects observed in the trial, either with the GM plants themselves, or on non-target organisms or the environment (attach additional pages if needed):			
Unless otherwise noted, check Yes or No in the appropriate box.		***YES***	***NO***
Are the unanticipated effects observed likely to affect the confinement of the GM material, or result in changes to confinement measures used?			
If yes, describe:			
Trial Manager Signature:		**Date:**	
Date Submitted:			

INTERIM REPORT FOR CONFINED FIELD TRIAL	
Trial Site:	**Location:**
Permit Numbers:	**Authorized Party:**
Reported By/Title :	**Phone/Fax:**
Planting Date(s):	**Harvest Date(s)**
Attach a complete report summarizing observations, methods of observation, data and analysis of experimental results, and any unanticipated effects observed. Provide an Executive Summary of the report in the space below (attach additional pages if needed).	
PI Name and Signature:	**Date:**
Date Submitted:	
REQUIRED ATTACHMENTS ▪ **Experimental Results and Conclusions**	

FINAL REPORT FOR CONFINED FIELD TRIAL			
Trial Site:		**Location:**	
Permit Number(s):		**Authorized Party:**	
Reported By/Title:		**Phone/Fax:**	
Planting Date(s):		**Harvest Date:**	
POST-HARVEST RESULTS			
Unless otherwise noted, check Yes or No in the appropriate box.		**YES**	**NO**
Has an Interim Report on experimental results been submitted to UNCST?			
Was monitoring for volunteers carried out during the post-harvest period according to requirements?			
Summarize observations on volunteers:			
Were all volunteers identified and destroyed prior to flowering?			
Method of Destruction:			
No volunteers have been observed on the trial site since (date):			
Were there any significant occurrences during the post-harvest period that may have affected confinement of the GM material?			
If yes, describe:			
Comments:			
PI Name and Signature:		**Date:**	
Date Submitted:			

10.0 Summary of Changes

PRIOR VERSION NUMBER	SUMMARY OF CHANGES
1	
2	
3	
4	

11.0 References

Berkey, D.A., Savoy, B.R., Miller S.R. and Johnson, P.G. (2002). Pollen dissemination from adjacent field of genetically enhanced cotton in the Mississippi delta. Proc. Beltwide Cotton Conf. Atlanta, GA.

Llewellyn, D. and Fitt, G. (1996). Pollen dispersal from two fields of transgenic cotton in the Namoi Valley, Australia. Mol. Breed. 2: 157 – 166.

USDA-APHIS. (2000). Minimum land, isolation, field and seed standards. 7 CFR 201.76, Table 5.

Appendix 1. MODEL STUDY PLAN

Study Title: [Descriptive title and year, used as header on all pages]

Principal Investigator: Individual
Postal address and contact details – phone, fax, email

Cooperating Investigators: Individuals, if any
Postal address and contact details – phone, fax, email

Table 1. Field Site(s) and Field Investigator(s)

Location(s)	Field Investigator(s) Name, Address and Phone Number
[physical location of field sites, gps of Trial site if available]	

Read and understood:

Field Investigator Date

1.0 PURPOSE

Brief description of the trial materials and objectives

2.0 REGULATORY COMPLIANCE

This field study contains regulated genetically modified plants. Therefore, strict adherence to regulatory requirements described in the Terms and Conditions of Authorization (date), and [other relevant standards] is required. All procedures, including this Study Plan and any Standard Operating Procedures (SOPs) relating to confinement of the regulated plant material must be read, understood and followed.

2.1 Specific procedures to be used in this study to comply with regulations include but are not limited to the following:

2.1.1 Ship and maintain regulated plant tissues so they are not released into the environment and are not mixed with non-regulated material. Shipments will be double contained and identified as containing genetically modified (GM) material.

2.1.2 Plant and label all plots in a manner to prevent inadvertent mixing of regulated plants with non-regulated plants.

2.1.3 [List specific and critical measures for genetic or material confinement, such as isolation distances, alternative methods of reproductive isolation, etc]

2.1.4 All plants in the Trial site [including border plants] must be destroyed at harvest time, by one or more of the following methods: [list approved methods].

2.1.5 Clearly identify the Trial site, including border rows using permanent landmarks or equivalent, to allow periodic monitoring of volunteer plants for a [one-year?] period following harvest.

2.1.6 Establish a monitoring program for volunteer plants in the Trial site to ensure that all volunteer plants in subsequent growing season (specific post-harvest restriction interval) will be destroyed. Monthly monitoring is required.

2.1.7 Do not plant the Trial site with a [list restricted crops] for minimum [post-harvest restriction] after harvest to allow monitoring of volunteers in the field in the following growing season. [List crops that may be grown in the Trial site following the study].

3.0 STUDY DATES

3.1 Proposed Start Date:

3.2 Proposed Termination Date:

4.0 DEFINITIONS

- **Alleyways** are unplanted areas between blocks or replicate plots.
- **Border rows or border plants** are the plants surround the plot area. In this study, the border rows are part of the Trial site and will be treated as regulated for purposes of destruction and disposal.
- **Field Site** is the entire facility including the building(s), roads, and entire acreage.
- **Isolation Zone** is the area between the Trial site and any cassava intended for food or feed usage.
- **Trial site** is the location that includes the experimental plants and border rows or plants.
- **List additional definitions critical to the study**

5.0 STUDY DESIGN

5.1 Starting Plants

Starting plants will be provided by [who?], and will be shipped to the Field Investigator according to all relevant regulatory requirements. [Shipment details may be added, if important]

Table 2. Summary of Test and Control Starting Materials

Material Code	Variety Identification	Lot Number	Phenotype
Test Varieties:			
Control Variety:			
Border variety:			

5.1.1 Characterization of Starting Material

[What characterization of the plants/seeds/starting material will be done before shipping?]

5.1.2 Starting Plants Shipment, Receipt and Storage

Movement of regulated genetically modified plants will follow strict adherence to requirements by using chain-of-custody forms to document receipt, storage, handling and disposition.

Record the total number of [plants, amount of seed, etc] received and planted. Cross-check identification or lot numbers with plant/bag labels.

Save all shipping containers for possible inspection by regulatory officials during the study period, if requested. If the shipping containers are destroyed, record the date and method of destruction.

5.2 Identification of Field Site and Plots

The Field Site is/are identified in Table 1.

The Trial site within the Field Site includes experimental plants and border plants. All four corners of the Trial site must be staked with durable markers such as metal or sturdy wooden stakes, so that the area can be identified during the study, and for the required post-harvest monitoring period.

Stake each row [or each plot] with line number and plot number (each row/plot must be staked with durable markers, such as a wooden or plastic stake or flag). All labeling and plot identification must be robust enough to last the entire study or be replaced as needed throughout the course of the study.

A site-specific field plot diagram identifies the unique randomization scheme of the plots in this study, and is given in Figure 1, below.

5.3 Description of Experimental Design

5.3.1 Field Design

The experimental plants will be planted in a [randomized complete block design/or other with xxx blocks or replicates]. Each block (replicate) will consist of xxx plots (xxx experimental lines and xxx control lines). Each plot will comprise x rows of xx plants each, or xx plants total. Plant spacing will be xx within plots and xx between plots, as shown in Figure 1.

Figure 1. Plot Design and Randomization

[Plot diagram, showing north direction]

5.3.2 Planting

It is expected that all plants/seeds will be planted or destroyed. Record details of planting and destruction of excess starting material on the appropriate forms.

5.3.3 Border Plants

[describe any provisions for border plants or rows]

5.3.4 Isolation Zone

Establish an isolation zone between regulated Trial site (including the border plants) and any [list prohibited plants]. **This zone must be at least xxx meters on all sides of the Trial site.** The isolation zone may be planted with [what crops], or any/all portions may be left fallow.

5.4 Agronomic Practices During the Growing Season

5.4.1 Maintenance Pesticides

It is important to maintain a normal agronomic crop with respect to disease, weed and insect infestations, by monitoring and treating (if necessary) in a timely manner. Maintenance pesticides applied for this study must be commercially registered products. Apply maintenance pesticides at the rate recommended on the manufacturer's product label. For each application, apply the maintenance pesticide to all plots and border rows uniformly at the same rate. Record all pesticide applications information (e.g., product, formulation, date applied, rate, and target pest) in the study notes.

5.4.2 Cultivation

Cultivate the Trial site as needed, in order to obtain an agronomically acceptable crop. Record all cultivation practices in the study notes.

5.4.3 Fertilizer

Uniformly fertilize all plots as needed in order to obtain an agronomically acceptable crop. Record all fertilizer applications as composition (percent N-P-K) and total amount (kg/ha) applied in the study notes.

5.4.4 Irrigation

Uniformly irrigate all plots as needed according to local practice, to produce an agronomically acceptable crop. Record irrigation amounts and dates in the study notes.

5.5 Observations

Collect and record the following data for each plot according to the method and frequency indicated.

5.5.1 Growth and Development

During the trial, take the following observations on each plot, at least [weekly/monthly], including the following observations: [observations and metric or scale to be used]. Note any unusual morphological effects or other unusual observations.

5.5.2 Harvest Observations

At harvest, record the following data for each [plant or plot]:

- [List required observations and metrics to be used]

Data will be pooled on a plot basis for analysis.

6.0 SAMPLING

Collect samples in the following order: (1) control plots, (2) test plots. To avoid cross contamination, thoroughly clean the sampling equipment between sampling of different plots.

To minimize protein degradation, place all tissue samples on dry ice **within 30 minutes after sampling.** Keep tissue samples frozen during transport from the Trial site to the preparation and storage facility, and until needed for analysis.

6.1 Sample Types and Procedures

6.1.1 [List required sample types, timings and amounts]

6.2 Sample Labeling

Durable, unique and clear sample labels that will be affixed to each sample container. If a coding system is used to label the sample containers, a copy of the cross-reference code index must be included in the study file.

6.3 Sample Handling and Storage

All plant tissue samples must be placed on dry ice in the field immediately following collection, within **30 minutes**. Tissue samples will be stored frozen in uniquely-labeled sample containers and maintained at dry-ice temperatures after collection.

Samples will be analyzed [where, when, by whom]. [List provisions for sample shipment, if any is anticipated, or 'No sample shipments are anticipated']. Appropriate precautions should be taken to ensure that samples will remain frozen during shipment, no leakage occurs between samples and all sample

packages are appropriately labeled.

7.0 SAMPLE PREPARATION AND ANALYSES

Sample preparation and analyses are not covered in this field trial Study Plan. [A brief description of the analyses to be done may be provided for informational purposes]

8.0 RECORDS TO BE MAINTAINED

8.1 Field Site Records

In addition to the specific information requested in this Study Plan, information on the study site must be provided, including:

a) A field site map showing access to the Trial site from local roads;
b) Trial site diagram showing the exact location of all plots in relationship to permanent landmark(s);
c) A description of the Trial site, including soil series and type, crops grown the previous season, and any other field data that may be relevant to this Study Plan.

8.2 Field Data Requirements

Record all study related data on forms provided, or record the relevant information on notebook pages. All forms, notes and other raw data, such as Sample Handling Forms, must be filled out promptly, accurately, and in indelible blue or black ink (no pencil). All entries must be dated on the day of entry, and signed or initialed by the person making the entry. If more than one individual records data on a page, it must be clear which individual recorded specific data. Any exact copies of raw data substituted for the original must be certified by the person making the copy.

Photographs showing the Trial site, sampling or other procedures are helpful in documenting the study. Photographs are strongly recommended for illustrating any abnormal growth or event that could affect the results. If possible, certify photographs by including photograph date, study, and signature/initials of the photographer.

8.3 Weather Data

The weather data required by this Study Plan or the duration of this study are maximum/minimum monthly air temperatures, monthly rainfall, and irrigation (if applied) including dates and amounts. Record any other weather data or events that may influence the conduct or integrity of the study. In addition to actual weather data, provide normal average monthly air temperatures (maximum/minimum) and rainfall data for a ten or more year basis from the nearest weather station (if possible).

8.4 Field Report

The Principal Investigator or his delegate will prepare and submit reports as required by regulations.

8.5 Record Retention

Always store the study file and notes in a secure location. Check the study file and all forms for completeness. All original raw data will be retained by the Principal Investigator after the completion of all required reports.

9.0 FIELD STUDY CONDUCT

9.1 Study Plan

This study will be conducted in accordance with this Study Plan and applicable Standard Operating Procedures (SOPs).

Document any planned change to this Study Plan prior to implementation, and document any unplanned change to the Study Plan or SOPs in the study file.

9.2 Reporting

All reporting required by the UNCST shall be completed in a timely manner. Retain copies of all Regulatory Authority and Authorized Party correspondence and reports in a file during the field study.

9.3 Destruction of Plant Material

Once the required samples are obtained, any crop residue, included in the entire field Trial site including border plants must be destroyed. [List approved methods of crop destruction].

9.4 Post Harvest Monitoring

A program for monitoring volunteer plants must be established to ensure that all volunteer plants in the subsequent growing season, a minimum of [post harvest period] after harvest, will be appropriately eliminated. Record the post harvest monitoring data according to SOP requirements on the forms provided.

10.0 QUALITY CONTROL RECOMMENDATIONS

Quality Control (QC) oversight to ensure scientific credibility is highly recommended and may be performed by a qualified technical party for the following segments of this plan:

- **a)** Facility and Record prior to trial establishment
- **b)** Planting
- **c)** Flower bud removal [or other critical phase, depending on the trial]
- **d)** Sampling
- **e)** Sample Shipment
- **f)** Study File Data Review

A qualified technical party may perform the QC functions for technical compliance with Terms and Conditions of Authorization, Study Plan and SOP requirements. If requested, access to the Trial sites must be allowed to Biosafety Inspectors and other agents of the UNCST.

11.0 REFERENCES

[List any references cited]

For more information contact:

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