

Appendix 1: Subject Information Sheet/ Consent Form

A randomised, controlled, assessor-blind, parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the treatment of head lice.

Subject Information Sheet

Thank you for offering to take part in a study which we hope will give us some very important information on the treatment of head lice. The treatments we will use are a mousse which contains the same ingredient used to kill head lice as other products currently available at the chemist, a well-known head lice treatment (a lotion), and a combing technique using a special head louse detection comb.

You will be treated with only one of the three products which will be decided by randomisation (a bit like tossing a coin). Before your treatment, the nurse will inspect your hair. The nurse will then teach a member of your family (or friend), how to treat your hair with the allocated treatment. Depending on the group that you are randomised into, the treatment will take a varying amount of time, but should take no longer than 2 hours.

If you are treated with either the mousse or the lotion, you will be treated only once. The nurse will then assess your hair 4 days, 7 days, 10 days and 14 days after treatment, to check that all the lice have been killed.

If you are randomised to the combing technique, your hair will be combed on 4 separate occasions over a 2 week period by the person who was trained at the start of the study (the adult carer). You will then be assessed by a nurse 14 days, 21 days and 28 days after you entered the trial to check that all the lice have been removed.

You will be asked to comment on the treatment you received, and then the trial will be finished.

You do not have to take part, or you may withdraw from the study at any time.

We do not expect you to have any side effects with your treatment, but if you feel uncomfortable at any time, please tell the study doctor or nurse immediately.

If you have any questions, at any time, please contact either Dr Pat Nair, Consultant in Communicable Disease Control (01582 744800) or Mrs Deirdre Power - study co-ordinator.

A randomised, controlled, assessor-blind, parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the treatment of head lice.

Subject Consent Form

I,.....

of (address).....

confirm I have agreed to participate in a study to evaluate the use of a new formulation of phenothrin head lice treatment versus phenothrin lotion and wet-comb technique in the treatment of head lice.

I have been informed of the potential benefits and hazards of treatment during this study and have been made aware of what is entailed for me as a participant in this study.

I understand that my name will not be disclosed in any report.

I understand that my giving of consent does not curtail my legal rights in any way.

I confirm that I, as far as I know, do not come within the terms of any of the exclusion criteria for the study as described by the investigator.

I agree to comply in good faith with the instructions given to me by the investigator and undertake to notify him at once if I suffer any unexpected and unusual symptoms or any deterioration whatsoever in my health or well-being. I will also notify the investigator if I take any other medication including prescribed or purchased products.

I have read and understood the subject information sheet.

I hereby signify my freely given consent to participate in this study and to undergo the therapy administration and examinations specified and necessary for the proper completion of the study, reserving my rights at any time to:

seek further information from the investigator concerning this study or the product to be studied.

withdraw my consent and terminate my participation in this study without prejudice. Likewise the investigator may withdraw me from the study if it is deemed necessary.

I will return all unused study product at the end of the trial in the pre-paid envelope provided.

A randomised, controlled, assessor-blind, parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the treatment of head lice.

Subject Consent Form continued

I agree that the Supervising Clinician will inform my General Practitioner of my participation in this study and of any information relating thereto which he/she considers relevant to the study.

I have been given the opportunity to ask any questions of the investigator undertaking the study, and understand and accept the replies provided.

Signature of Subject:

Date:

I confirm that I have fully explained the nature, purpose and reasonably foreseeable risks of the study to the subject.

Name of investigator (block capitals):

Signature of investigator:

Date:

I confirm that the investigator duly explained the nature, purpose and possible risks of the trial to the subject and that this contract was signed by the subject and the investigator in my presence.

Name of Witness (BLOCK CAPITALS):

Signature of Witness:

Position:

Date:

Parent/Guardian Information Sheet/Consent Form

A randomised, controlled, assessor-blind, parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the treatment of head lice.

Parent/Guardian Information Sheet

Thank you for offering for your dependant to take part in a study which we hope will give us some very important information on the treatment of head lice. The products we will use are a mousse which contains the same ingredient used to kill head lice as other products currently available at the chemist, a well-known treatment (a lotion) for head lice and a combing technique using a special lice head louse detection comb.

Your dependant will be treated with only one of the three products which will be decided by randomisation (a bit like tossing a coin). Before the treatment, the nurse will inspect his/her hair. The nurse will then teach either yourself or a member of your family (or friend), how to treat your hair with the allocated treatment. Depending on the group that your dependant is randomised into, the treatment will take a varying amount of time, but should take no longer than 2 hours.

If your dependant is treated with either the mousse or the lotion, he/she will be treated only once. The nurse will then assess his/her hair 4 days, 7 days, 10 days and 14 days after treatment, to check that all the lice have been killed.

If your dependant is randomised to the combing technique, his/her hair will be combed on 4 separate occasions, over a period of 2 weeks, by the person who was trained at the start of the study. He/she will then be assessed by the nurse 14 days, 21 days and 28 days after entry to the trial to check that all the lice have been removed.

Your dependant will be asked to comment on the treatment he/she received, and then the trial will be finished.

Your dependant does not have to take part, or may withdraw from the study at any time.

We do not expect him/her to have any side effects with the treatment, but if he/she feels uncomfortable at any time, please tell the study doctor or nurse immediately.

If you have any questions, at any time, please contact either Dr Pat Nair, Consultant in Communicable Disease Control (01582 744800) or Mrs Deirdre Power - study co-ordinator (01525 874095).

A randomised, controlled, assessor-blind, parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the treatment of head lice.

Parent/Guardian Consent Form

I,.....

of (address).....

confirm I have agreed to my dependant participating in a study to evaluate the use of a new formulation of phenothrin head lice treatment versus phenothrin lotion or wet-combing in the treatment of head lice.

I have been informed of the potential benefits and hazards of treatment during this study and have been made aware of what is entailed in this study.

I understand that my dependant's name will not be disclosed in any report.

I understand that my giving of consent does not curtail my dependants legal rights in any way.

I confirm that my dependant, as far as I know, does not come within the terms of any of the exclusion criteria for the study as described by the investigator.

I agree to comply in good faith with the instructions given to me by the investigator and undertake to notify him/her at once if my dependant suffers any unexpected and unusual symptoms or any deterioration whatsoever in health or well-being. I will also notify the investigator if my dependant takes any other medication including prescribed or purchased products.

I have read and understood the parent/guardian information sheet.

I hereby signify my freely given consent for my dependant to participate in this study and to undergo the therapy administration and examinations specified and necessary for the proper completion of the study, reserving my rights at any time to:

seek further information from the investigator concerning this study or the product to be studied.

withdraw my consent and terminate my dependant's participation in this study without prejudice. Likewise the investigator may withdraw my dependant from the study if it is deemed necessary.

All unused study products will be returned at the end of the trial

A randomised, controlled, assessor-blind, parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the treatment of head lice.

Parent/Guardian Consent Form continued

I agree that the Supervising Clinician will inform my dependant's General Practitioner of his/her participation in this study and of any information relating thereto which he/she considers relevant to the study.

I have been given the opportunity to ask any questions of the investigator undertaking the study, and understand and accept the replies provided.

Signature of Parent/Guardian: _____

Date: _____

I confirm that I have fully explained the nature, purpose and reasonably foreseeable risks of the study to the parent/guardian.

Name of investigator (block capitals): _____

Signature of investigator: _____

Date: _____

I confirm that the investigator duly explained the nature, purpose and possible risks of the trial to the parent/guardian and that this contract was signed by the subject and the investigator in my presence.

Name of Witness (BLOCK CAPITALS): _____

Signature of Witness: _____

Position: _____

Date: _____

Appendix 2 - Declaration of Helsinki

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly
Helsinki, Finland, June 1964
and amended by the
29th World Medical Assembly
Tokyo, Japan, October 1975
35th World Medical Assembly
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my subject will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act only in the subject's interest when providing medical care which might have the effect of weakening the physical and mental condition of the subject".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease. In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research, a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a subject, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world.

Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimise the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately

informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

- 10 When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
- 11 In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's guardian.

- 12 The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every subject - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the subject to participate in a study must never interfere with the physician-subject relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).

III NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN

SUBJECTS

(Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers - either healthy persons or subjects for whom the experimental design is not related to the subject's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

Appendix 3 - Guidelines on Good Clinical Research Practice

GOOD CLINICAL RESEARCH PRACTICE

In order to comply with the principles of good clinical research practice, all parties involved in the evaluation of medicinal products share the responsibility of accepting and working according to the standards set out in the "CPMP Guidelines on Good Clinical Practice for Trials on Medical Products in the European Community", and in the "ABPI Guidelines on Good Clinical Research Practice". These principles are relevant to all four phases of clinical investigation of medicinal products.

In line with these guidelines, the responsibilities of investigators in relation to the trial are set out below:-

The personal integrity and welfare of the trial subjects are the ultimate responsibility of the investigator, who must also ensure that appropriate medical care is maintained after the trial.

Subjects enrolled in a trial should be provided with a card bearing information identifying that he/she is in a trial if appropriate. Contact addresses/telephone numbers should be given in case of action needed at another place.

In the medical records it should be clearly marked that the subject is participating in a clinical trial.

The family doctor should normally, with the subject's consent, be informed.

Any information becoming available during the trial which may be of relevance for the trial subjects, must be made known to them by the investigator.

To ensure that he/she is fully familiar with the properties of the investigational medicinal product(s) as described in the Investigator's Brochure.

To ensure that he/she has sufficient time to conduct and complete the trial, and has adequate staff and appropriate facilities (including laboratories) which are available for the duration of the trial, and to ensure that other trials do not divert essential subjects or facilities away from the trial in hand. The investigator may nominate (if appropriate) a local study co-ordinator to assist in administration of the trial.

To obtain local Ethics Committee approval where appropriate, and provide a copy of the Ethics Committee approval to the sponsor.

To present to the sponsoring company a global figure for the cost of conducting the trial at that particular centre.

To provide retrospective data on numbers of subjects who would have satisfied the proposed entrance criteria during preceding time periods in order to assure an adequate recruitment rate for the trial.

To submit an up-to-date CV and other credentials to the sponsor.

To agree and sign the protocol submitted to the ethics committee. No changes should be made to the study without agreeing them with the sponsor, except when necessary to eliminate an apparent immediate hazard to the subjects. Any change should form a protocol amendment appended to the protocol and signed by the investigator and sponsor, for which the investigator should obtain further ethics committee approval if appropriate.

To obtain informed consent from trial subjects prior to inclusion in the trial. The investigator should provide a specimen copy of the informed consent form to be used where this is not provided by the sponsor.

To provide information to all staff members involved with the trial or with other elements of the subjects' management, at the same time ensuring that the confidentiality of all information about subjects is respected by all persons involved, as well as the information supplies by the sponsor.

To ensure that deliveries from the sponsor of investigation medicinal products are correctly received by a responsible person (e.g. a pharmacist) and are recorded; that investigational products are handled and stored safely and properly and are only dispensed to trial subjects in accordance with the protocol; that any unused products are returned to the sponsor. At the end of the trial, it must be possible to reconcile delivery records with those of usage and returned stocks. Account must be given of any discrepancies. Certificates of delivery and returns must be signed.

To satisfy himself/herself that the medicines labelling requirements are met

To ensure that the trial code envelopes are kept safe, and that they are returned intact, if not used, to the company at the end of the study. The treatment code should only be broken in accordance with the protocol and the sponsor should be consulted/informed when this is done.

To ensure the data and case report forms are complete and accurate, and are recorded in accordance with the protocol. Any corrections to data recorded must be made in such a way as not to obscure the original entry. In addition, all records relating to the study, including copies of case record forms, should be maintained for as long as is practicable - the European Guidelines state 15 years.

Clinically significant abnormal laboratory values or clinical observations must be followed up to the subjects benefit after completion of the trial. To notify (with documentation) the sponsor and when applicable the ethics committee (and relevant authorities when required) immediately in the case of serious adverse events.

To agree with and sign the final report of the trial. For multiple trials the signature of the co-ordinating investigator may suffice if agreed in the protocol.

As always, it is important for investigators to maintain an accurate set of his/her own subject notes. This is essential source material for auditing purposes. At any stage during the trial, the investigator has the responsibility to make all data available to the sponsor/monitor and/or relevant authority (where required) for verification/audit/inspection purposes. This includes audits by Quality Assurance personnel from the sponsor company.

Appendix 4 - Clinical investigation of medical devices for human subjects
The European Standard EN 540

European Standard EN 540 - Role of the Clinical Investigator

The clinical investigator shall ask the sponsor for information as described in the clinical investigator's brochure and any other information he judges essential for the conduct of the clinical investigation. He shall be well acquainted with the use of the device.

The clinical investigator shall be well acquainted with the clinical investigation plan before signing it.

The clinical investigator shall ensure that he and his team will be available to conduct and complete the clinical investigation.

Any other concurrent clinical investigation conducted by him shall not give rise to a conflict of interest or interfere with the specific clinical investigation in hand.

As far as the clinical investigation is concerned, the clinical investigator shall be responsible for the personal safety and well being of subjects

The clinical investigator will make the necessary arrangements, including emergency treatment, to ensure the proper conduct of the clinical investigation.

The clinical investigator shall endeavour to ensure an adequate recruitment rate of subjects during the clinical investigation.

If appropriate, subjects enrolled in a clinical investigation shall be provided with some means of identification that they are taking part. Contact address/telephone numbers shall be given and the medical records shall be clearly marked. Note, the subjects physician should, with the subject's agreement, be informed.

Subjects who cannot be expected to derive any direct therapeutic benefit shall be examined to ascertain their state of health before entering the clinical investigation. Subjects shall be invited to confirm by a signed declaration that they have disclosed all matters concerning their health and any current medication shall be recorded.

The clinical investigator shall ensure that adequate information is given to the subject (or his guardian or legal representatives) both in oral and written form, on the nature of the clinical investigation. This information shall be easily understandable by the subject. This information shall include the aims, expected benefits for him and/or others, risks and inconveniences and an explanation of any alternative methods, and of possible consequences of any withdrawal from the clinical investigation. Payment or any other form of inducement to subjects who cannot be expected to derive any direct therapeutic benefit, shall only be for expense, time and inconvenience. The subject shall be made aware that there are procedures for compensation and treatment if he is injured/disabled by participating in the clinical investigation. Subjects shall be given the opportunity to enquire about the details of the clinical investigation. The information shall make clear to the subject that he remains free to refuse to participate or to withdraw from the clinical investigation at any stage without any sanction. Subjects shall be

allowed sufficient time to decide whether or not they wish to participate. The subject shall be informed that his participation in the clinical investigation is confidential. He shall be made aware that the data relating to the study may be made available to third parties while maintaining anonymity.

A subject who wishes to withdraw from the clinical investigation shall be informed of the possible consequences of this withdrawal, by the clinical investigator.

The clinical investigator shall obtain informed consent preferably in writing. Following national policy, informed consent shall be documented either by the subjects dated signature or by the signature of an independent witness who records the subject's assent. Note: Obtaining informed consent from some categories of subjects raises particular ethical and legal issues which need special consideration (see Declaration of Helsinki).

The clinical investigators shall document how informed consent will be obtained and recorded in emergency circumstances where the subject is unable to give it. In the exceptional case when neither signed informed consent nor witnessed signed oral consent are possible, each case shall be documented and reported to the ethics committee and the sponsor with the reasons, by the clinical investigator.

The clinical investigator shall be responsible for submitting the clinical investigation plan for opinion or approval to an appropriate ethics committee and shall transmit the results to the sponsor. If not already included in the clinical investigation plan, the clinical investigators shall also provide the ethics committee with at least information on the following:-

- a) an assessment of the scientific merit of the proposal, taking into account the pre-clinical data.
- b) possible effects on the health of the subjects
- c) possible hazards and facilities available to deal with them
- d) the degree of discomfort and distress foreseen
- e) proposed method of supervision of the clinical investigation and the responsibilities of the clinical investigators
- f) any monetary or other inducements, to be offered to subjects
- g) arrangements to be made between the sponsor and the clinical investigator
- h) the procedures for obtaining consent from the subject or where appropriate, their guardians or legal representatives.
- i) provisions for compensation in the event of injury or death arising from participation in a clinical investigation and any insurance or indemnity to cover the liability of the clinical investigator and sponsor.

- j) the methods of maintaining subjects confidentiality.

The clinical investigator shall inform the ethics committee and ask for its opinion or approval regarding any significant change in the clinical investigational plan that has been approved by the sponsor, and the reasons for the change. The clinical investigator shall inform the ethics committee of any severe adverse device effect.

The clinical investigator shall inform without undue delay the sponsor and the monitor (if applicable) about any severe adverse event, about all adverse device effects and provisions made.

The clinical investigator shall have primary responsibility for the accuracy, legibility and security of all clinical investigation data, documents and subject records both during and after the clinical investigation. The case report form shall be signed by the clinical investigator. Any alteration of the raw data shall be signed and dated, the original entry being retained for comparison.

The clinical investigator shall discuss with the sponsor any question of modification of the clinical investigation plan and shall obtain his written agreement.

In any emergency situation, the clinical investigator shall exercise his judgement to safeguard the subject's interests. In that case deviations from the clinical investigation plan shall not require the prior approval of the sponsor or the ethics committee. Such deviations shall not be considered as a breach of agreement and shall be reported to the sponsor.

The clinical investigator shall make sure that the clinical investigation plan is followed by all members of the investigation team, and by other parties involved in the execution of the clinical investigation. Any significant deviation shall be recorded.

The clinical investigator shall specify and document a procedure for recording adverse events and adverse device effects and reporting severe adverse effects and all adverse device effects to the sponsor.

The clinical investigator shall be responsible for the supervision and assignment of duties to the members of the clinical investigation team. He shall be responsible for the measures needed to maintain confidentiality.

After the clinical investigation, the clinical records and investigation data shall be kept by the clinical investigators for an appropriate time and the subjects identity shall not be released to third parties without the subjects prior consent.

**Appendix 5 - Letter from Bedfordshire Health to schools
inviting participation in clinical trial.**

Dear Headteacher,

Bedfordshire Health, jointly with national experts from the Medical Entomology Centre in Cambridge, and under funding from Seton Healthcare Group plc, are embarking on a study to evaluate a potential new way of treating head lice. This new treatment is hoped to be just as effective as treatments which are currently available, but easier to use.

It is hoped that around 320 children or adults will be recruited to this trial over the next few months. There will be no cost to the school. We should be grateful if you are willing to co-operate.

On your approval, you will be sent a batch of letters that will be addressed to the pupils' parent/guardian. These letters will include a reply slip. Any person who has head lice, and who wishes to be included in the trial, will be asked to contact the study co-ordinator (Mrs Deirdre Power) on 01525 874095.

Those people who replied will then be contacted by Deirdre Power and no further participation will be required from the school.

Some information is included for your perusal, and we look forward to hearing from you soon.

Yours faithfully,

Dr. P Nair
Consultant in Communicable Disease Control

I am willing for my school to be included in the trial to study a potential new treatment for head lice.

Headteacher: -----
School Address: -----

Phone Number: -----

Reply to: Mrs Deirdre Power, South Bedfordshire Healthcare Trust, Wigmore Lane
Health Centre, Wigmore Lane, Luton, LU2 8BG.

**Appendix 6 - Letter from Bedfordshire health to Parents/Guardians
inviting participation in clinical trial**

Dear Parent/Guardian,

Bedfordshire Health, jointly with national experts from the Medical Entomology Centre in Cambridge, and under funding from Seton Healthcare Group plc, are embarking on a study to evaluate a potential new way of treating head lice. This new treatment is hoped to be just as effective as treatments which are currently available, but easier to use.

Your child's/dependant's school has agreed that we send these letters out to all pupils within the school. In total we need to recruit around 270 patients with head lice.

Briefly, the trial will involve a treatment period, and a follow up period (to check the treatment worked). During this time a nurse will visit you on a number of occasions. For this reason, to enter the trial you would have to be available for visits over the next month. You will be asked to comment on your thoughts on the treatment received. There will be no cost to yourself, and the work will be done in your own home, so there will be no travel inconvenience.

If anyone in your family has head lice, either now or over the next few months, and you would like them to join the study, please send the enclosed letter to Mrs Deirdre Power, South Bedfordshire Community Healthcare Trust, Wigmore Lane, Health Centre, Wigmore Lane, Luton, LU2 8BG. Alternatively, you can contact Mrs Deirdre Power on 01525 874095.

Some information is included for your perusal.

We look forward to hearing from you soon.

Yours faithfully,

Dr. Pat Nair.
Consultant in Communicable Disease Control

Appendix 7 - Letter from Bedfordshire Health to Patient's GP

Dear Colleague,

Bedfordshire Health, jointly with national experts from the Medical Entomology Centre in Cambridge, and under funding from Seton Healthcare Group plc, are embarking on a study to evaluate a potential new treatment for head lice. This new treatment is hoped to be just as effective as treatments which are currently available, but easier to use. The trial is expected to include 320 patients who complete treatment.

I am writing to inform you that _____ who is a patient of yours, has been entered into the trial following their written informed consent. We have excluded patients from the trial who have a known sensitivity to pyrethroid and/or chrysanthemums; patients who have been treated with another head lice product within the last 4 weeks; patients who have any persistent skin disorder of the scalp (i.e. eczema, chronic dermatitis, psoriasis); patients who suffer from asthma; patients who have been treated with antibiotics over the last 4 weeks; patients who have bleached hair, or hair which has been colour treated or permed within the last 4 weeks; pregnant or nursing mothers; patients who have participated in another clinical trial within 1 month prior to entry; and patients who have already participated in this clinical trial. As far as we are aware, your patient does not fall into any of these categories.

If you have any patients who may be eligible to enter into the trial, please contact the study co-ordinator, Mrs Deirdre Power on 01525 874095.

Yours faithfully,

Dr Pat Nair
Consultant in Communicable Disease Control

Appendix 8 - Information Document

The company sponsoring the study is: Seton Healthcare Group plc
 Tubiton House
 Medlock Street
 Oldham
 OL1 3HS
 Tel: 0161 652 2222

The Principal Investigators are: Dr Pat Nair (also Supervising Clinician)
 Consultant in Communicable Disease Control
 Bedfordshire Health Authority
 Luton

Ian Burgess - Deputy Director
 Christine Brown - Medical Entomology Nursing
 Sister
 Medical Entomology Centre
 Cambridge
 Tel: 01223 414316

The Study Co-ordinator is: Deirdre Power
 Community Nurse Immuniser
 South Bedfordshire Community Healthcare Trust
 Tel: 01525 874095

Study Information

Around 270 people will be recruited into the study. We hope the study will give us some very important information on a new product for the treatment of headlice. The product is a mousse which contains the same ingredient used to kill headlice as other products currently available at the chemist. We think however, that the mousse will be easier to use.

We will compare the mousse with another product often used to kill headlice, and the Wet-comb technique. Treatment will be with one of these methods.

There will be a period following the treatment, whereby the hair will be assessed by a nurse (three or four times) to check the treatment worked. The whole study period will take no longer than one month.

There will be no cost, and as the tests are done in the home, there will be no travel inconvenience. There will also be no commitment to stay in the trial, should you want to withdraw.

For further information, please contact either Ian Burgess / Christine Brown at the Medical Entomology Centre, or Deirdre Power on the numbers shown above.