To: Chief Executive of NPSA

Date: 3rd May 2011

Re: Complaint

Ref. 10/H0206/32 submission date 24.05.2010
Assessing the feasibility and acceptability of comparing the Lightning Process with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) pilot Randomized Controlled Trial. (SMILE)
http://www.bristol.ac.uk/ccah/research/childrencomplexhealthneeds/chronic-fatigue/smile.html

I wish to submit a formal complaint about the conduct of the SW 2 Regional Ethics Committee and the National Research Ethics Service in their handling of the above study application. I would like to make it clear that my complaint is not intended as an appeal against an REC decision – I am aware that there is no appeal process for third parties against REC decisions. Please also note that my complaint is in no way vexatious in intention. I have no personal or professional relationship with the researchers and no vested interest in this study. The purpose of my correspondence with the REC – which commenced in October 2010, after ethics approval had been granted - has been with a view to bringing to the REC's attention new information that I believe warrants a review of their favourable opinion. I was pleased that the REC did conduct a review, but they failed to address the fundamental issues raised by that new information, and they have subsequently failed to take into account further new information, which seriously compromises the validity of the study and more importantly, compromises the rights and welfare of the research participants and their parents. I use "parents" to indicate the adults with personal responsibility for the patients. My concerns relate to the rights, safety, dignity and well-being of the paediatric patient participants and their parents and to the professional conduct of the National Patient Safety Agency, which I believe has breached its stated remit in the context of this study application. I believe I also have both a right and a duty to report concerns that criminal offences may have been committed and that the spirit of the law and regulations may not have been upheld. Please be aware that my complaint and any response received may be placed in the public domain in the public interest.

Areas of complaint

. Conduct of the Chief Investigator (CI), which I believe the REC did not use Standard Operating Procedures (SOPs) to deal with, and which may amount to research-related fraud and misconduct.
. Conduct of the REC in handling the original study application and the review of its opinion.
. Conduct of the NRES once the matter had been referred on.

Summary of specific concerns

1. Failure to declare or treat this as an application for approval of a clinical trial.
2. Failure to disclose risks and material information to the REC and study participants.
3. The REC relied too heavily on the views and opinions of the CI, which are in contradiction of medical and scientific evidence provided to the REC by concerned parties.
4. The REC failed to take sufficient account of the lack of impartiality of the care organisation supporting the study and of the External Advisory Group.
5. The reasons given by the CI why children should be used as test subjects for this intervention before first testing it on adults are unsubstantiated and contradicted by existing scientific evidence.
6. The reasons given by the CI to justify this research were not evidence-based.
7. Reasons why the research could not be justified were evidence-based yet were dismissed as

largely matters of opinion.

8. Patients'/parents' right to give informed consent to participate in the study has been undermined by the following:

8.1 The study participants are the patients of the CI, recruited by her at her specialist NHS clinic at the point of initial diagnosis, which is likely to positively and prejudicially influence the primary outcome of the study – recruitment and retention.

8.2 Non-disclosure of risk to participants in the study proposal.

8.3 Non-evidence-based declaration of risk as slight following ethics review.

8.4 Non-disclosure that the information regarding the success rate of the intervention and regarding the underlying causes of ME/CFS (and other diseases) in the advertising of the intervention cannot be relied on as it is unsubstantiated, and given that patients'/parents are specifically advised in the study protocol to read such information – this inevitably makes promise of therapeutic gain even if therapeutic gain is not promised directly in the patient information leaflets. Therefore, participants are subject to coercion in breach of the Declaration of Helsinki and their human and civil rights.

8.5 Financial incentive to participate given that the LP costs upwards of £620. With no risk declared initially, and then only "slight" risk declared after ethical review, and with claims of such high success rates in the advertising material that they have been directed to read, incentive to patients/parents to try a product that is already on the market, in addition to the standard care they would normally receive, is inevitably high, particularly for less wealthy families.

8.6 Non-disclosure that practitioners administering the intervention are currently breaking the law by breaching Consumer Regulations and are under surveillance by the Trading Standards Service and the Advertising Standards Authority.

9. Given that the Phil Parker Group is in beach of consumer regulations and under surveillance by Trading Standards for false and misleading claims, aggressive selling and illegal marketing practices, the effect of exposure to advertising of the product under evaluation on the study outcomes. If the intervention were a drug in a blinded trial, exposure to such aggressive sales techniques in the product's advertising would be likely to increase the placebo effect in the control group. As a psychotropic intervention in a non-blinded trial, such expectations of recovery as promised from the advertising are likely to influence the paediatric patient's belief that they are recovered, and their inclination to say they feel better when they may not. No biomedical tests are being used to assess the impact of the intervention – only subjective measurements using questionnaires focussing on the patients' moods and feelings - even though it is claimed that the intervention affects the patient's physiology and is being tested as a treatment. This not only compromises the scientific value of the study but increases the risks of psychological and physical harm to the participants.

10. The dignity, safety and well-being of a vulnerable group of minors are being put at an indefensible degree of risk by the DH/NHS/NPSA by entrusting their care to practitioners who are not medically or clinically qualified and are breaking the law.

11. As a result of the above, criminal offences may have been and may be currently being committed.

Failure to declare a clinical trial.

I believe that the REC was not qualified to assess this application and that it should have been assessed by a Type 3 REC.

At **A61** on the **NHS REC form**:
*"**Summary of the study. Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review."***

"The overall aim is to study the feasibility and acceptability of conducting a randomized controlled trial (RCT) to investigate the effectiveness and cost effectiveness of Specialist Medical Care compared to Specialist Medical Care plus the Lightning Process in treating CFS/ME in children. This study uses qualitative methods to understand the issues that relate to the successful design and implementation of a full scale RCT"

At ***A6-2*** **Summary of main issues**, the CI wrote:

"*The main objective for this study is to assess the feasibility and acceptability of conducting a RCT investigating the effectiveness and cost effectiveness of Specialist Medical care compared to specialist medical care plus the Lightning Process. This is important because over 250 children a year receive the Lightning Process for CFS/ME and there are currently no reported studies investigating the effectiveness or complications of the Lightning Process in children. As with all interventions, proper evaluation is necessary."*

SMILE is a pilot study that involves the child participants being subjected to an intervention that has yet to be tested for its safety, yet in reply to **Q2** on the NHS REC form, Dr. Crawley selected:

"*Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology*".

While the intervention is not a medicinal product – it is nevertheless a commercially available product. Claims for its efficacy in ME/CFS rest on its supposed ability to affect the physiology of the test subject. Phil Parker, inventor of the Lightning Process and member of the research team, claims that the LP works by acting upon what he describes as the patient's Physical Emergency Response (PER). The REC and NRES repeatedly refer to the LP as a treatment. It was noted by the lead researcher and the REC that there is no existing scientific data on the safety or efficacy of LP. At A12 in the study application:

"there are currently no reported studies investigating "the effectiveness or complications" of the Lightning Process in children"

I believe this was all the more reason to apply extreme caution in the process of consideration for ethical approval for experimenting on children. In the absence of such scientific data, any reports of the safety and efficacy of the LP are inevitably anecdotal, whether positive or negative. Consequently, I believe that the study should have been assessed with the additional rigour that applies to a CTIMP. At the very least, the CI should have indicated the study as "other research" in the proposal and I believe the REC should have noticed this discrepancy and acted accordingly, as per SOPs.

Failure to disclose risk.

I believe it was a serious omission by the CI to state in her application that she did not believe there to be any risks to participants in the study and that it was a serious error on the part of the REC to allow this to go unchallenged prior to its original decision to grant approval. As the MHRA website states:

"*No product is risk free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.*"

The LP is not medicinal but is nevertheless a product with advertising claims that it can treat disease by effecting physiological changes in the patients. I note that the Chief Investigator together with the sponsor is responsible for ensuring that the documentation submitted to the ethics committee fully and accurately describes the safety profile of the product to be tested and the potential risks to participants and that the ethics committee may generally rely on the accuracy of this information. I believe that the REC was misled by the CI by this non-disclosure of risk. However, I also believe the committee failed to adequately address this issue once it had been drawn to its attention. While the REC did recommend inclusion of risk in the patient information as a result of the review of its favourable opinion, its judgement that those risks were slight was based on no available evidence, yet in the face of information from a number of respected care organisations, as well as from individuals with direct experience of the intervention, that showed the contrary. It may be argued that the lack of available evidence is one reason why this study should be done, yet that is all the more reason to apply caution in the patient information and to be honest with the participants and their parents that the risks are as yet unknown and cannot be quantified. All reports of the effects of this intervention – both positive and negative – are currently anecdotal. Some of that anecdotal evidence shows there to be a risk of a serious adverse event during the study, i.e. requiring hospitalisation or persistent or significant disability or incapacity. The CI should have been aware that serious adverse reactions by patients having done the LP have been reported. I believe the right to informed consent has been compromised by non-disclosure of risks to patients already recruited to the study by the time of the review, and to all participants by not disclosing that the risks are as yet scientifically unquantifiable and therefore could range from slight to severe, or from low to high. I believe that a criminal offence may have been committed in this matter.

Failure to justify this research.

"PART B: Section 7 - Children
1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group."
"Children will be recruited between 12 and 18 years of age.
CFS/ME is different in children and adults with different risk factors, course and outcome. It is therefore not possible to complete a study in adults and extrapolate the results to children. At the moment, over 250 children currently use the Lightning Process as an intervention for CFS/ME. It is important to evaluate this intervention in children."

I believe that the CI misled the REC by claiming that ME/CFS in children has different risk factors, course and outcomes to those of adults, citing this as reason why this study should be done with children before the LP has been first tested on adults. The CI appears to have produced no scientific evidence to validate that claim, but included 4 journal citations with no quotes or explanation, that upon inspection do not support the CI's claim, but in fact tend to contradict it.

I believe it was negligent of the REC to "*accept the researcher's view*" on this, given that guidance is clear that research should not be carried out on children if it can feasibly be done with adults first. Phil Parker claims that the LP is equally effective in adults and children. Research published in

September, which the REC ignored completely during its review, showed the same biomedical findings in children as had previously been found in adults – evidence of persistent viral infection - adding to the existing body of scientific evidence that ME/CFS is the same in adults and children. NICE and the CMO do not differentiate adult-child ME. I believe the research applicant misled the REC and that the REC was negligent in accepting only her view on this crucial issue.

At ***A12*** on the application form, in reply to the question, ***"What is the scientific justification for this research?"*** the CI wrote:

"In 2009, over 250 children attended groups to access the Lightning process as an intervention for paediatric CFS/ME*."*

I believe the REC was negligent in failing to ask for evidence to support this claim. My rationale for querying the truth of the claim stems from the aggressive selling practices known to be employed by the Phil Parker Group. In the survey cited by the CI at the ethics review as an indication that the LP fared better than other therapies, only 101 people altogether (not time-related) of some 4000 who completed the survey had actually done the LP and no distinction was made regarding age. In the absence of evidence, I believe the research applicant may have been misled regarding the numbers of children with ME/CFS doing the LP or that she herself was misleading the REC. In any case, I believe the REC was negligent in accepting this as valid justification for this research. As was pointed out to them, parents try a range and number of alternative therapies in their desperation to help their sick children recover. The LP is advertised as a cure for ME/CFS and other diseases in that full recovery is promised – it is not simply advertised as a technique that some patients may find helpful – it is therefore unsurprising that parents who can afford upwards of £620 will be willing to allow their children to try it. If the sheer number of those doing the LP was justification for selecting this particular intervention for research, then evidence of that number should have been provided and the potential risks to the intervention should have been declared.

While the recruitment process had commenced with the authority of the original approval decision by the REC, the CI was aware that the ethics service had received a substantial amount of correspondence raising a number of serious concerns and objections to the study and that an ethical review was taking place due to the weight of this correspondence, yet she proceeded with the recruitment phase of the study. Given the seriousness if the issues at stake, I believe that research governance may have been breached, and given that this pilot study is in effect a clinical trial, I believe that a criminal offence may have been committed. It is repeatedly claimed that this pilot study is needed to evaluate treatments and the participants are being subjected to an intervention that has not yet been assessed for its safety – I believe that to be a breach of research governance as well as a breach of good medical practice and duty of care.

<u>Further conduct of the REC</u>

Although the study proposal had the support of two organisations that were directly involved in the project - Action for ME and The Association for Young People with ME - the REC would have been aware of the widespread concern raised by publicising of the original study proposal. I gather several FOI requests were submitted and statements were issued by impartial individuals, individuals having undergone the LP themselves, as well as long-standing and highly-regarded patient organisations with direct experience and knowledge of the intervention concerned that together represent the views and interests of thousands of patients with ME/CFS. In fact, most well-established ME/CFS patient groups raised valid concerns and objections to the study proposal, other than the two charities directly involved with it – also bearing in mind that the CI is medical advisor to one of those two charities (AYME) so it is not impartial with regard to this study. I believe that this should have led the REC to subject the proposal to far greater scrutiny, requiring

evidence to substantiate the views and claims of the CI, and that the matter should have been referred to a committee with the experience and expert knowledge necessary to properly address and assess the various issues raised. The REC could have opted to engage the assistance of a referee and could have invited external observers to the committee meetings. However, I believe that the issues raised were fundamental and that the proposal should have been withdrawn or rejected at that stage.

During the review of its favourable opinion, I believe the REC should have given far more careful consideration to the matters raised by care organisations such as The ME Association, Invest in ME, the 25% Group (for the 25% most severely affected ME patients) and perhaps most importantly, given that the research involves minors, the REC should have given more weight to the views and evidence provided by the longest-running and Queen's award-winning children's ME charity, The Young ME Sufferers Trust. Again, the REC could have opted to engage the assistance of a referee and could have invited an external observer to the committee meetings. I believe that the REC gave far too much weight to the views and claims of the CI at review, which she was unable to substantiate with evidence. I believe the REC also gave too much weight to the letter of support provided for the review meeting by AYME's CEO Mary-Jane Willows. The letter was emotive in tone and vexatious in that it included disparaging and unfounded remarks about those who had raised objections to the study and was entirely based on her own claims and opinions without any evidence provided to support them. That letter should not have been used to influence the opinion of the REC to the extent that it did, in preference to the matters raised by all the other care organisations and new evidence provided.

It was clear from the minutes of the review meeting that the REC had not noticed that the LP trainers that would be administering the intervention to the children were not medically or clinically qualified and I do not believe that adequate child protection precautions have been taken. The study outline states that a 20 minute phone call will take place, which cannot be supervised unless it is fully audio-recorded and that the LP trainer will visit the home alone. LP is a psychotropic intervention. Parents of sick children are also a vulnerable group and I do not believe that sufficient account has been taken of this for their protection.

While the amendments to the patient information suggested by the REC at the meeting in December had been a result of ethical review, the study had already started - a large number of participants had already been recruited and would have read the existing patient information – their informed consent was compromised and invalidated by the important non-disclosure of risks to participating in the study – it is not the case that the disclosure of risk was based on new evidence – it was based on the fact that no intervention carries nil risk and evidence that the intervention does carry risk was available to the CI and the REC prior to the original favourable opinion. No response has been given by the NRES or the research team to enquiries as to whether and how patients already recruited and their parents have been informed of the ethical review and the changes to the patient information.

The REC was selective in the issues it addressed in the review of its favourable opinion. This raises questions about the rationality of implementing a decision review procedure in which the REC whose original decision was called into question, was permitted to review its own effectiveness. The REC failed to address the submission of evidence that new research would contraindicate both the safety of the product to be tested and the premise on which its supposed efficacy is based. The research in question was published in September 2010. In my letter to the AW 2 REC, I wrote:

"All the biomedical research carried out to date shows the pathology of ME/CFS to be the same in adults as in children. The most recent example of this is UK research published in September 2010 that shows evidence of persistent viral infection in children with M.E, which is consistent with the

same results found in adults with ME in 2005. It is my belief that this evidence was not available to the ethics committee at the time of its decision.

Biochemical and Vascular Aspects of Paediatric Chronic Fatigue Syndrome:
http://www.meresearch.org.uk/research/projects/children.html

The implications of this research for the study were not considered at the review meeting.

The committee failed to address the issues arising from new information regarding the trading practices of The Phil Parker Group in their marketing of the Lightning Process. The minutes read:

3. "*It was noted that the judgement of the ASA was made after the submission of the application to the ethics committee .And corrective action had been taken*".

That the ASA ruling had been made after submission of the application had been pointed out by complainants and therein lay the significance of the concern, i.e. that the subject of the ASA ruling was one of the two LP traders in the research team – Alastair Gibson – and that the ruling applied to his advertising of the Lightning Process, which he trades under the name of Withinspiration. At the time of the ruling, the ASA's powers did not extend to website content. Corrective action was taken by removing the offending sponsored advertisement but Alastair Gibson had not complied with the implication of that ruling by amending the content of his website, which included an abundance of unsubstantiated claims of success for the LP and misinformation about ME/CFS (in addition to other medical conditions), along with advertising of the study in question with a link to the details on the Bristol University website. I have evidence of this as I submitted a complaint to Trading Standards myself at the time – October 2010 – i.e. after the REC had granted approval. I had only looked at the Withinspiration website out of interest in the SMILE study – the flouting of Consumer Regulations was blatantly obvious and littered throughout the website. You will note from the study documents that potential recruits for the study were advised to read the content of the LP website – they would therefore have been subject to unsubstantiated claims about the LP – not only about its alleged high success rate but that any lack of success was attributed to the participant not doing it properly – such claims inevitably have a psychological impact – they are likely to influence the patients' decision to participate in the study and likely to influence their motivation to say that the LP has worked when it may not have – what child wants to fail? I accept that the REC has no role in evaluating the intervention itself in a study proposal, however, evidence about the content of the sales literature and its likely effect on participants was factual and material to the study and I believe the committee's lax approach to considering these issues was negligent. Even after ethical review, the website contained misleading claims and information – I know this because I was asked by the investigating officer at Trading Standards to check whether any changes had been made to the website and advised him accordingly. The main LP website – i.e. of Phil Parker himself – had similar unsubstantiated claims and misleading information – as confirmed by Trading Standards. I gather over 40 LP practitioners have been the subject of ASA/Trading Standards investigation. Under the circumstances, I believe it unethical to use children as test subjects in order to provide evidence of whether these advertising claims may be eventually substantiated or not. Also from the minutes of the ethics review:

4. "*Mr Parker is shortly to attend court for making false claims about his product. The Committee noted the correspondence submitted by Dr Crawley from Mr Parker and the refutation of this. The Committee considered this but had no further comments to make on this point".*

I have no personal knowledge of the matter of court attendance, but Phil Parker was the subject of complaint to Trading Standards regarding his false claims about the Lightning Process. Given that the REC did not appear to have sought evidence from the complainant of the validity of this complaint, it should have accepted as new information that should warrant a further review of its

favourable opinion when a letter of confirmation was sent to the NRES on 31st March 2011 that Phil Parker was under investigation by Trading Standards and would be subject to legal action if he refused to comply with the law. I believe the REC/NRES is acting against its remit by allowing independent practitioners under surveillance for unlawful trading practices access to paediatric patients – including lone home visits - and is failing in its duty of care to those patients and their parents. I believe this may amount to criminal negligence.

Conduct of NRES

That the Phil Parker Group – and specifically that the two traders included in the research team – Phil Parker and Alastair Gibson - were in breach of the law relating to Consumer Regulations at the time the study proposal was being advertised publicly and at the time of the review, had been subject to adjudication by the Advertising Standards Authority while the study was being advertised, and are currently under investigation by the Trading Standards Service has not been adequately addressed by the NRES. The matter was also reported incorrectly and misleadingly by the NRES to the public – and hence to the study participants and their parents. These significant errors have not been corrected by the NRES. I believe that the study participants and their parents have a right to know that the Phil Parker Group and the Lightning Process are under investigation by the Advertising Standards Authority and Trading Standards as this information materially affects their ability to give informed consent. Mrs. Kirkbride's response to the letter was that she notes that LP practitioners have in the past complied with the law "*when advised to do so*". Dr. Wisely said that she had already considered the matter as part of her investigation, which pre-dated the letter from Trading Standards, which suggests that the NRES knowingly published false information about this matter in the apology to Phil Parker. I doubt that this complies with SOPs.

I submitted a complaint to Dr. Wisely regarding the false and misleading information given to me by Mrs. Kirkbride by way of the apology to Phil Parker for an error in the minutes of the review meeting and in email correspondence. This related to withholding of the information that the "entity" she referred to as having been the subject of the ASA ruling in fact belonged to Alastair Gibson, over whose business practices she said Phil Parker no control and with whom she said Phil Parker has no financial or other interest, when in fact Alastair Gibson was the other LP practitioner named in the study outline and is licensed by Phil Parker to trade the Lightning Process; and related to her withholding the information that Phil Parker himself was the subject of investigation by Trading Standards. Mrs. Kirkbride had also informed me that it was never intended that Alastair Gibson would be directly involved in the study, yet the evidence shows this to be untrue. Mrs. Kirkbride had specifically asked that the correction to the minutes containing the false information be publicised and she was also aware that her correspondence with me was in the public domain and that my letter of response to the ethics review had been co-signed by 90 others. Dr. Wisely replied that this matter had been dealt with as part of her own investigation. I accept that Dr. Wisely may have dealt with the matter internally within the NRES but I remain dissatisfied that I was given false information; that I was asked to publicise it; that said false information will be available to research participants, their parents and the public; and that no action has been taken by the NRES to correct that false information, which remains in the public domain at the NRES' request.

Dr. Wisely carried out an investigation in response to a complaint from a third party. The notes of the discussions held for the purpose of her investigation state: *"JW explained that the key element of the complaint was the SOPs themselves, regardless of whether or not they had been followed".*

As the matter of whether SOPs themselves were followed does not appear to have been fully addressed, I am not satisfied that this matter has already been thoroughly and fully investigated. I do not believe that SOPs were followed for this research application, or that the underlying principles of ethical guidance were applied, in favour of the protection of the physical and

psychological safety and well-being of the paediatric research participants. I agree that current SOPS provide the flexibility for RECs to review their favourable opinions in the light of new information, but I strongly disagree with the view of Andrew George that,

"*the new information was more a weight of opinion*."

Material facts have been provided to the REC/NRES in new information – as an independent inquiry would show. This contrasts with the lack of factual evidence provided for justification of this study and the weight given by the REC to the opinions of the CI and the CEO of AYME. I believe that public assurance has been breached with respect to the protection of the rights, safety and well-being of clinical trial subjects, as should be consistent with the principles that originate in the Declaration of Helsinki.

It was noted that the NREAP: "*felt that in reviewing its decision the REC involved should limit itself to considering only the relevant new information regarding the study itself and not to consider allegations which were outside of its remit or competence to comment upon.*"

In practice, the REC failed to address new information and questions regarding the safety of the study, and appears to have been highly selective in those matters it chose to consider.

"The panel stated that it was important to conduct impartial research into ME and that, where appropriate, it was equally important to ensure the benefits of research are extended to children in line with existing guidelines. It was noted that in the SMILE study participants were not being deprived of current care and the research question was the effectiveness of the additional tool which the study was designed to evaluate. "

In practice, the REC failed to take account of the lack of impartiality in this research; that benefits of research were not being extended to children as such, as there was no existing evidence that children may benefit by this research; and that the research was not being extended to children within existing guidelines, as existing guidelines were not being followed.

The ethics service failed to realise that concerns did not relate to the children being deprived of what they describe as normal care, but related to the failure by the lead researcher to disclose the risks of undergoing the "*additional tool"* under evaluation in the study, along with other concerns as previously described. The REC also failed to properly assess those risks, judging them to be slight with no evidence on which to base that judgement.

I also wish to raise complaint about this comment:

"*The panel expressed their concern that research into ME was becoming increasingly difficult for researchers and that consequently less research was being undertaken in this important disease area. Given the potentially vexatious nature of correspondence and complaints, it was agreed that AG should contact 'Understanding Animal Research' to explore areas of common ground in handling correspondence with regard to conducting research in contentious areas.*"

I object to the accusation of potentially vexatious complaints. The panel should perhaps consider the effect on correspondents who had taken the trouble to provide the REC with important and material new information, of the lack of proper consideration by the REC of the facts and ignoring of evidence provided, as evidenced by the minutes of the review meeting. The panel should also consider the effect on correspondents such as myself and the 90 co-signatories to a response to those minutes, of the considerable length of time taken by the NRES to consider their response to points they should already have addressed during their review. The panel should be aware of the

effect on correspondents meanwhile, of the apology issued by the NRES to Phil Parker which showed that evidence provided to the REC on this issue had been ignored by the REC and which was phrased in such a way as to mislead as to material facts and which put untrue information in the public domain. The panel should be aware of the level of concern among correspondents that children were being put at risk while the NRES response was awaited. Had the study been suspended pending the NRES' response, correspondents need not have felt the sense of urgency for the NRES/REC to consider new information that correspondents clearly felt should warrant further review of the REC's favourable opinion. SOPs should provide sufficient protection for child research participants without the need for recourse to guidance on animal research.

I feel that an apology for this statement casting aspersions on the motives of correspondents is warranted. I am also aware of the issues causing difficulties in ME/CFS research and do not believe this provides justification for this particular study.

All the statements made herein are made to the best of my knowledge and belief and in good faith.

(Patient Advocate)
3rd May 2011

Encs.:
Letter to SW2REC 10.10.2010
Extracts from Alastair Gibson's website Withinspiration dated 10.10.2010
NRES letter and minutes of ethics review meeting 6.1.2011
Response to NRES letter and minutes of ethics review meeting 16/24.1.2011
NRES public apology to Phil Parker 4.2.2011 – 14.4.2011
Correspondence with Mrs. Joan Kirkbride re: apology to Phil Parker 8.2.2011-1.4.2011
Letter to Mrs. Kirkbride re: media report by AYME president 14.2.2011
Correspondence with Dr. Janet Wisely 5.4.2011-14.4.2011
Dr. Wisely's NRES complaint investigation 25.3.2011
Dr. Wisely's notes of SMILE investigation interviews 22.3.2011
Letter from Trading Standards Service 31.3.2011
Reply from Joan Kirkbride and Hugh Davies to response to ethics review meeting 6.4.2011
Extracts from NPSA/NRES SOPs
Some patient accounts of the Lightning Process: http://web.me.com/johnsayer23/LP/Home.html