1 – Ethical approval forms for all changes to the protocol

UCL RESEARCH ETHICS COMMITTEE GRADUATE SCHOOL OFFICE



Professor Russell Viner INCLUSIVE Programme Institute of Child Health 30 Guilford Street UCI

30 January 2014

Dear Professor Viner

Notification of Ethical Approval

Project ID: 5248/001: INCLUSIVE trial: initiating change locally in bullying and aggression through the school environment

I am pleased to confirm that your study has been approved by the UCL Research Ethics Committee for the duration of the project i.e. until January 2015.

Approval is subject to the following conditions:

 You must seek Chair's approval for proposed amendments to the research for which this approval has been given. Ethical approval is specific to this project and must not be treated as applicable to research of a similar nature. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing the 'Amendment Approval Request Form'.

The form identified above can be accessed by logging on to the ethics website homepage: http://www.grad.ucl.ac.uk/ethics/ and clicking on the button marked 'Key Responsibilities of the Researcher Following Approval'.

It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. Both non-serious and serious adverse events must be reported.

Reporting Non-Serious Adverse Events

For non-serious adverse events you will need to inform Helen Dougal, Ethics Committee Administrator (ethics@ucl.ac.uk), within ten days of an adverse incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Chair or Vice-Chair of the Ethics Committee will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

Reporting Serious Adverse Events

The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator immediately the incident occurs. Where the adverse incident is unexpected and serious, the Chair or Vice-Chair will decide whether the study should be terminated pending the opinion of an independent expert. The adverse event will be considered at the next Committee meeting and a decision will be made on the need to change the information leaflet and/or study protocol.

On completion of the research you must submit a brief report (a maximum of two sides of A4) of your findings/concluding comments to the Committee, which includes in particular issues relating to the ethical implications of the research.

With best wishes for the research.

Yours sincerely

Professor John Foreman

Chair of the UCL Research Ethics Committee

Cc:

Anne Mathiot, INCLUSIVE Programme Trial Manager Professor Terence Stephenson



Amending an Approved Application

Should you wish to make an amendment to an approved study, you will need to submit an 'amendment request' for the consideration of the Chair of the UCL Research Ethics Committee. Applications can only be amended after ethical approval has been granted.

You will need to apply for an amendment approval if you wish to:

- 1. Add a new participant group;
- 2. Add a new research method;
- 3. Ask for additional data from your existing participants;
- Remove a group of participants or a research method from the project, and have not yet commenced that part of the project;
- 5. Apply for an extension to your current ethical approval.

If you need to apply for an amendment approval, please complete the Amendment Approval Request Form on the next page.

When completing the form, please ensure you do the following:

- Clearly explain what the amendment you wish to make is, and the justification for making the change.
- · Insert details of any ethical issues raised by the proposed amendments.
- Include all relevant information regarding the change so that the Chair can make an informed decision, and submit a copy of the sections of your application that have changed with all changes highlighted/underlined for clarity.
- You do not need to submit your original application in full again. However, if the changes you wish to
 make alters several sections of your application form, you are advised to submit this.

One signed hard copy of the form (and any amended documents), as well as an electronic copy of these same documents must be submitted to the REC Administrator to the address detailed below:

Administrator of the UCL Research Ethics Committee
Room 3.03 (3rd floor) (for hand delivery use buzzer: 3rd Floor Director of Academic Services)
2 Taviton Street
University College London
London WC1H 0BT

Email: ethics@ucl.ac.uk

Amendment requests are generally considered within 5-7 days of submission.



	1	1 *	me and Address of Principal estigator:
r			f Russell Viner
-	Project Title: INCLUSIVE trial: Initiating change locally in bullying and aggression through the sentironment		ying and aggression through the school
	3	3 Type of Amendment/s (tick as appropriate)	
	 ☐ Research procedure/protocol (including research instruments) ☐ Participant group ☐ Sponsorship/collaborators ☐ Extension to approval needed (extensions are given for one year) ☐ Information Sheet/s ☐ Consent form/s 		
		Other recruitment documents	
		☐ Principal researcher/medical supervisor* ☐ Other *	
		*Additions to the research team other than the principal researcher, do not need to be submitted as amendments but a complete list sho	
	4	Justification (give the reasons why the amendment/s are needed) The study executive team thought it would be in the interest of the study to add a question on bullying perpetration. This will add a new secondary outcome to the study and an additional question in the students' questionnaire delivered in Year 2 and Year 3. The protocol has been amended accordingly in secondary outcome section as well as a minor correction in the statistical section.	
		See the question added below.	
	-	Details of Amendments (provide full details of each amendments have been made and attach all amended and new documenta. This is coming from the Centers for Disease Control and Prevente measures [1]. The only measure that it recommends that for perpetration is the Modified Aggression Scale Bullying subsexisting, established measure with evidence of reliability.	tion) rention (CDC) guidance document on bullying uses on specific occasions of recent bullying
		References	
5		Hamburger, M.E., K.C. Basilem, and A.M. Vivolom, Measi Bystander Experiences: A Compendium of Assessment To- Control and Prevention, National Center for Injury Prevention at 2. Bosworth, K., D.L. Espelage, and T.R. Simon, Factors school students. Journal of Early Adolescence, 1999. 19: p. 34	ols. 2011, Atlanta, GA: Centers for Disease and Control. associated with bullying behavior in middle
		The added question is as per below:	
		How many times have you done the things below in the last th	ree months?
		1 .	3 or 4 times 5 or more times) 19h. (Never, 1 or 2 times, 3 or 4 times, 19mmes, 5 or more times)
		- I threatened to hit or hurt another student. (Never, 1 or 2 time	es, 3 or 4 times, 5 or more times)

I was given extra homework to do (Never, 1 or 2 times, 3 or 4 times, 5 or more times)
 Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s)
 None

6 All students are explained at the beginning what the study is about and why we need their opinion. All students are provided with an Consent Form and can choose not to complete the questionnaire. Parents can opt out too after receiving an Information letter 10 days before the survey delivery.

Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- For student projects I confirm that my supervisor has approved my proposed modifications.

Signature:

Date: 09/03/16

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Amendments to the proposed protocol have been ... What we will be the Research Ethics Committee.

Date: 23 3 20(6.



1	Project ID Number: 12/153/60 5248/101. Name and Address of Principal Investigator:	
	Prof Russell Viner	
2	Project Title: INCLUSIVE trial: Initiating change locally in bullying and aggression through the school environment	
3	Type of Amendment/s (tick as appropriate)	
	 □ Research procedure/protocol (including research instruments) □ Participant group □ Sponsorship/collaborators □ Extension to approval needed (extensions are given for one year) □ Information Sheet/s □ Consent form/s □ Other recruitment documents □ Principal researcher/medical supervisor* □ Other * 	
	*Additions to the research team other than the principal researcher, student supervisor and medical supervisor do not need to be submitted as amendments but a complete list should be available upon request.	
4	Justification (give the reasons why the amendment/s are needed) The approved Inclusive Protocol mentions: the "Intervention funding was obtained from the Educatio Endowment Fund (EEF), which also funded an independent evaluation of effects on educational attainment to be conducted by the University of Manchester". To enable the Manchester team to do a independent evaluation, we now need to update our Consent form and parents information sheet to it the participants and allow them to provide an informed consent. The Manchester team has already submitted their project to their Ethics Committee and have received approval (email attached, ethics reference number 15584 in University of Manchester). Their EC application described in great details protocol followed to transfer data safely and adhere strictly to the 1998 Data Protection Act.	
5	Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) Following discussion with UCL R&D team, we have been advised to submit an amendment to our Education of the consent form and Parent Information Sheet as per attached, used for the year 2 are surveys (April to July 2016 and 2017). The independent evaluation means some data will be transferred to the Manchester team for them to able to proceed with their analysis. The Manchester team will also access the National database to loo school and student attainment. These 2 aspects have been cover in our changes to the forms attached. The 2 document we would like to change to enable the Manchester team for proceed are: - The Student Consent form (the 2 paragraphs added are in yellow): Text added: "I understand that the information collected during the survey will be used to support or research in the future, and may be shared anonymously with other researchers* and "As part of the st we will also be looking at exam results (year 9 SATS, year 10 estimates, and GCSES), to see if we help improve schools and young people's attainment. You do not have to do anything extra, and the discompletely anonymous. If you would rather we didn't use this data, please tick the box below: (a checking box) I would prefer that my academic data not be used in this study" - The parent Information sheet (the changes are in yellow in the document): Text added:	
	*The information collected during the survey will be used to support other research in the future, and may be shared anonymously with other researchers	

As part of the study, we will also be looking at exam results (year 9 SATS), to see if we can help improve schools and young people's attainment. The data is completely anonymous.

Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s) The Manchester team has already submitted their project to their Ethics Committee and have received

approval (email attached, ethics reference number 15584 in University of Manchester). Their EC application described in great details the protocol followed to transfer data safely and adhere strictly to the 1998 Data Protection Act.

Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

We met with UCL R&D to discuss the way to ensure we are doing the right thing during this process and are following their lead with this amedment.

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- For student projects I confirm that my supervisor has approved my proposed modifications.

Signature:

Date: 20/01/16

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- Include all relevant information regarding the change so that the Chair can make an informed decision, and submit a copy of the sections of your application that have changed with all changes highlighted/underlined for clarity.
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University College London
London WC1H 0BT

Email: ethics@ucl.ac.uk

Amendment requests are generally considered within 5-7 days of submission.





	1	Project ID Number: 5248/001	Name and Address of Principal Investigator:		
			Prof Viner, UCL Institute of Child Health 30 Guilford Street, WC1N 1EH		
2		Project Title: INCLUSIVE Trial: initiating change locally in environment	n bullying and aggression through the school		
	3	3 Type of Amendment/s (tick as appropriate)			
		Research procedure/protocol (including research instruments) Participant group Sponsorship/collaborators Extension to approval needed (extensions are given for one year) Information Sheet/s Consent form/s Other recruitment documents Principal researcher/medical supervisor* Other radiations to the research team other than the principal researcher, student supervisor and medical supervisor do not need to be submitted as amendments but a complete list should be available upon request. Justification (give the reasons why the amendment/s are needed) Following our meeting with UCL Ethicas Committee (EC) on the 23 January, it was agreed that we would change our student Consent form as well as the Parent Information sheet to reflect the meeting outcome The question to the Ethics Committee was: When to treat an early age of first time sexual experience as an SAE? We believe that the following is an ethically sound response to data on sexual activity obtained from the INCLUSIVE study questionnaires. A. We treated any clear disclosure of potential harm as an SAE and informed the school about the situation and the student involved. There were a small number of cases (2) where the young person wro additional text on the survey form that indicated potential harm e.g. a report of being forced (note the survey form did not have free text options relating to the sexual health questions but these young people wrote this beside their answers on the survey papers). B. Any report of sexual activity below age 10 should be treated as an SAE and reported to the school. We do not consider that report of starting sex over age 10 years should be reported as an SAE for the reason outlined above. We chose <10 because: 1) the World Health Organisation defines adolescence as 10-19 years; 2) given the lower age of puberty in modern Britain, and 3) given the median age for starting sex is 14-15 years in modern Britain, this is more than 2 SD below the mean. We believe that choosing an age above this risks harm to large numbers by potenti			
	4				
	5	Details of Amendments (provide full details of each amer have been made and attach all amended and new docume Following discussion with the EC, it was agreed that the	ndment requested, state where the changes entation)		

providing:

- the Student Consent form would be updated with an additional statement: "if your responses reveal significant harm (give examples of what would constitute 'significant' harm) to yourself and others then we would be duty bound to breach confidentiality and inform the appropriate authorities for your own safety and/or the safety of others."

The updated consent form is attached, changes highlighted in yellow.

The research team feels that we wouldn't include this in the parental information as a) parents aren't giving formal consent and b) it might cause abusive parents to withdraw children from research (And we might then miss an opportunity for the student to report abuse).

Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s)
The Ethical issues have been discussed during the meeting on the 23 January.

- 1. We have a duty to protect children. In doing so we need to balance promoting the autonomy of young people i.e. not unnecessarily breaching confidentiality with promoting their wellbeing. It is possible that breaching confidentiality in response to reports of very early sexual intercourse may possibly prevent child sexual abuse or provide support to those who have experienced child sexual abuse.
- It could therefore be argued that all reports of sex before 16 years should be considered an SAE and therefore reported to the authorities.
- Starting sex under age 16 years is 'normative' involving around one-quarter of young people. Treating this as an SAE would produce great harm.

If we were to treat early sex as an SAE, we would thus be obliged to break confidentiality and report young people's sexual experiences to their school or to social services or police. These professionals would then have a duty of care to investigate every single case –potentially for up to a quarter of the year (and a third in some schools).

Given that the great majority of young people are extremely not likely to have been abused, this would represent a major breach of their autonomy with concomitant upset as well as producing other potential harms such as undermining teacher-student and school-parent relationships. Furthermore, schools being required to mount safeguarding interventions with up to a third of their students would mean that such responses would be highly likely to be inappropriate and therefore very likely cause more harm than benefit.

We believe it is extremely likely that these harms would markedly outweight any benefits that may result for children.

3. There is no evidence that starting sex early is harmful.

The law is designed to protect young people from exploitation. Merely starting sex early is not itself necessarily a cause of harm; we do know that young people who start sex early may be more likely to have an STI – although this results from not using protection, not from the actual age of starting sex.

Those with responsibility for child protection do not act on a <16 disclosure unless they have grounds to suspect harm to young person or someone else (such as a power difference between partners, including age, or coercion).

In our study, we avoided questions that involved potential harm (e.g. coercive sex) because we did not want to have to break confidentiality.

This approach is common to many of the general surveys of adolescent health that have included questions on sexual behaviour.

We believe that only evidence of harm is reasonable justification for disclosure. Otherwise researchers could never do research into any behaviours that are illegal – for example, even simply talking on the phone while driving, drug taking, sex work.

Our survey gathers information on a range of behaviours that are not legal but are not SAEs

Note that our survey also gathers information on a range of behaviours that are technically not legal for 14 year olds — e.g. smoking, drinking and drug use. We also gather information on antisocial behaviours including some which are illegal (e.g. property damage; assault), all of this approved by the ethics committee in our original proposal. None of these are accorded SAE status, for the same reasons outlined

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in (3) above. Note that routine government surveys of crime and of smoking, drinking and drug use in adolescents would not be feasible if behaviour considered illegal was therefore considered to be an SAE.

Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- For student projects I confirm that my supervisor has approved my proposed modifications.

Signature: Prof Russell Viner

Date: 30/01/17

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Amendments to the proposed protocol have been approved by the Research Ethics Committee.

Interim M. Heinrich

Signature of the REC Chair, Professor John Foreman: M. Hamel

Date: 8/2/2017 ·



1	Project ID Number: 5248/001	Name and Address of Principal Investigator:
	-	Prof Russell Viner
2	Project Title: INCLUSIVE trial: Initiating change locally in environment	oullying and aggression through the school
3	Type of Amendment/s (tick as appropriate)	
	□ Research procedure/protocol (including research instruction of participant group) □ Sponsorship/collaborators □ Extension to approval needed (extensions are given for of information Sheet/s) □ Consent form/s □ Other recruitment documents □ Principal researcher/medical supervisor* □ Other *	ne year)
	*Additions to the research team other than the principal research do not need to be submitted as amendments but a complete list	er, student supervisor and medical supervisor should be available upon request.
4	Justification (give the reasons why the amendment/s are needed) The current approved protocol (v1.5) had some details missing in the Process Evaluation section of the	
5	Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) Additional details added in Yeloow in the updated main protocol (v1.6) attached to this email: - Section Trial arm fidelity: "(from year 3 annual)" and "We will also draw on administrative documents (e. minutes, attendance sheets, training satisfaction feedback)" - Section Reception and responsiveness: "We will also interview n=2 students involved in restorative practice sessions per year in each case study school."	
6	Ethical Considerations (insert details of any ethical issues None All students are explained at the beginning of each intervie opinion. All students are provided with an Consent Form an	w what the study is about and why we need their
7	Other Information (provide any other information which yo during ethical review of the proposed changes)	u believe should be taken into account
	Declaration (to be signed by the Principal Researcher) I confirm that the information in this form is accurate to tresponsibility for it. I consider that it would be reasonable for the proposed at For student projects I confirm that my supervisor has appropriate the projects of the principal Researcher)	mendments to be implemented.



Signature:

Date: 06/10/16

FOR OFFICE USE ONLY:



	1	Project ID Number: 5248/001	Name and Address of Principal Investigator:	
Ī			Prof Viner, UCL Institute of Child Health 30 Guilford Street, WC1N 1EH	
	2	Project Title: INCLUSIVE Trial: initiating change locally in bullying and aggression through the scholenvironment		
	3	3 Type of Amendment/s (tick as appropriate)		
		□ Research procedure/protocol (including research instead of participant group □ Sponsorship/collaborators □ Extension to approval needed (extensions are given for Information Sheet/s □ Consent form/s □ Other recruitment documents □ Principal researcher/medical supervisor* □ Other *		
		*Additions to the research team other than the principal resear do not need to be submitted as amendments but a complete list		
		Justification (give the reasons why the amendment/s and There are some planned deviations to the original study of the changes. The deviations and rationales for these are provided below 1. Annual telephone interviews: The protocol indicate teaching staff annually (year 1-3) across 40 schools (interview protocol for Year 1. We do not intend to conduct staff interviews with 1 SLT member across 40 schools (interview Rationale: Interviews in year 2 were considered unnecess (e.g. via interviews with action team members, curriculum is progressing in intervention schools. Some control school interviews, so we have reduced the number of interview in-depth case studies of intervention schools (and away to	protocol. Our TSC and the NIHR have approved low: es conducting interviews with 1 SLT and 2 revention and control). These are completed as per it telephone interviews in Year 2. We will conduct ention and control) in Year 3. sary since we are already collecting other data in surveys, focus groups) on how the intervention tools have also reported overburden following Year was for Year 3. Resources are being re-directed to	
	4	 Researcher observations of curriculum delivery: \(\) session in each school but are now using a curriculum st ordinator in each school to capture what was delivered, \(\) will also be conducted. 	urvey circulated to the intervention curriculum co-	
		Rationale: The lead intervention facilitator advised us tha administrative burden for schools and our modified appro- component.		
		Action group meeting observations: This will be	done in n=10 schools rather than n=20 schools.	
		Rationale: We are collecting substantial amounts of othe harvesting of all action group documentation. The obsen provided by facilitators and do not need to be done acrost time that would have been spent on this to more in-depth	vations act as a check on the validity of diary data as all 20 schools. We will redirect the researcher	

Case study schools: The protocol originally specified case studies in n=4 control schools; and n=4
intervention schools. We now plan to conduct case studies in n=6 intervention schools only.

Rationale: Control schools have also complained about overburden and we think that asking too much of them may threaten follow up rates in the trial. The main purpose of the case studies is to capture data on intervention mechanisms. Case studies of control schools will not be informative about mechanisms, it will only inform us about what activities constitute the control condition in the trial, about which we are already collecting across all control schools. We have re-directed resources so that we are doing more work in intervention schools (n=6 schools as case study sites; conducting 1 focus group with staff; and 2 focus groups with students in each school).

Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation)

The deviations from the original protocol are provided below (this is within the Process Evaluation section):

- Annual telephone interviews: The protocol indicates conducting interviews with 1 SLT and 2 teaching staff annually (year 1-3) across 40 schools (intervention and control). These are completed as per the protocol for Year 1. We do not intend to conduct staff telephone interviews in Year 2. We will conduct interviews with 1 SLT member across 40 schools (intervention and control) in Year 3.
- Researcher observations of curriculum delivery: We originally intended to observe N=1 curriculum
 session in each school but are now using a curriculum survey circulated to the intervention curriculum coordinator in each school to capture what was delivered, how and when. Interviews with curriculum leads will
 also be conducted.
- Action group meeting observations: This will be done in n=10 schools rather than n=20 schools.
- Case study schools: The protocol originally specified case studies in n=4 control schools; and n=4
 intervention schools. We now plan to conduct case studies in n=6 intervention schools only.
- 6 Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s)
- Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- · For student projects I confirm that my supervisor has approved my proposed modifications.

Signature: Prof Russell Viner

Date: 05/10/15

FOR OFFICE USE ONLY:

Signature of the REC Chair, Professor John Foreman: ..

Date: \$18/2015.