Young SMILES

RESEARCHER STANDARD OPERATING PROCEDURES (SOPs)

Version 4 – 15.08.2017

The SOPs outlined in this document are to be followed throughout the Young SMILES feasibility trial.

The SOPs/documents included are as follows:

If you have any queries please contact Judith Gellatly, Trial Manager
email: judith.l.gellatly@manchester.ac.uk; phone 0161 3067672.

Please ensure that these SOPs are used alongside your own University/Trust lone working guidance and procedures. Knowledge from GCP training should also be taken into account throughout the trial.

An overview of the recruitment procedures for each site can be found in Appendix 1.

Initial Phone Call - Checklist

Please tick to confirm you have performed these checks

Family ID -

[Prior to phoning the patient (on receipt of the Consent to Contact Form) you should have uploaded the details to the spreadsheet and allocated an ID number]

• Family details correct	☐
• Alternative contact details (for family) discussed if applicable	☐
• Family given opportunity to discuss trial and ask questions Young SMILES Information Booklet Parents-Carers v1.1 31.05.17 Young SMILES Information Booklet 6-11 v1.0 23.03.17 Young SMILES Information Booklet 12-16 v1.1 31.05.17	☐
• Ensure are still interested in taking part	☐
INITIAL SCREENING	
• Who in your family would be interested in taking part in the study? _____	☐
• CHECK INCLUSION CRITERIA ☐ Parents/carers experiencing an SMI (psychosis, dual diagnosis, severe depression, personality disorders) ☐ Children 6-16 years ☐ Children in contact with the ill parent/carer >10 hrs ☐ Children have some awareness of the parent's mental illness	☐
• CHECK EXCLUSION CRITERIA ☐ Children of parents diagnosed with common mental health problems (e.g. mild-moderate depression) ☐ Children who cannot participate in group work (due to severity of problems, learning difficulties, etc). ☐ A parent/carer/significant family member or friend would be willing to attend parent sessions	☐
• Explain next steps	☐
• Provide researcher contact telephone number/email and availability	☐
• Inform family that they will be contacted on a fortnightly basis to be informed of progress and potential waiting time to randomisation	☐
• Input details into spreadsheet and make a note of when to re-contact Young SMILES Family Spreadsheet	☐
• Inform JG of progress	☐

Initial Phone Call - Protocol

1. Introduction

Please use this protocol when contacting a potential family for the first time after they have expressed an interest in taking part in the trial.

2. Expression of interest in trial

Families may express an interest in taking part in the trial in three ways:

- Completing and returning a *Consent to Contact* form to the research team
- Asking a practitioner/support worker to complete and return a *Verbal Consent to Contact* form on their behalf
- Contacting a member of the research team directly

The usual trigger for making contact with a family will be receiving a copy of a completed *Consent to Contact* form. However, if a family member actively contacts you (by phone/email) to discuss the trial further and then indicates that they would like to participate, please make sure you complete a *Consent to Contact* form for that participant.

On receipt of a *Consent to Contact* form **assign a Young SMILES ID** to the family and enter this on the *Consent to Contact* form. IDs should be generated as follows:

Site ID - (Coventry for Coventry, N for Newcastle, W for Warrington)
Three digit number - (starting at 01 for the first family)
Role in family* - (ID for each family member taking part by adding **P**(**Parent**), C(**Carer**), Y(**Young Person**))
Age band of child* - (**A1** for 6-11, **A2** for 12-16)

***it is likely that you will not be able to add these until you have met with the family during the baseline appointment.
If more than 1 parent/carer/young person is taking part in the family then allocate them a number starting from 1. The 'index child' who will complete the questionnaires should be Y1.

For example, if the first family in Warrington with 1 parent and 2 children (aged 9 (index child) and 13) the family members would be given the following IDs:
W01P1A1
W01Y1A1 – index child
W01Y2A2

Prior to contacting the family enter all the details provided on the *Consent to Contact* form into the Young SMILES spreadsheet.

This form must always be stored in a lockable filing cabinet, which is locked when not in use, and **never** left unattended.

3. Contacting Families

Once an initial ID has been allocated please contact the family, via their preferred contact method. For the majority this is likely to be by telephone. Be mindful if you are phoning the family member (particularly if it is a mobile number) that they may not be a position to talk at that moment. If this is the case arrange to re-contact them on a day/time that is convenient for them.
When you contact a person by telephone ensure that you are speaking to the correct person before you explain who you are and what you are calling for. Disclose the reason that you are calling if you feel it is appropriate.

When you call explain who you are and the reason for calling and thank them for returning their form. Ask them if they are still interested in the Young SMILES trial and ask if they have any questions that they have. You may need to remind them about what the study involves, if allocated to the group where it would take place etc.

Once they have had the opportunity let them know that you have a couple of short questions that you were wondering if they could answer to ensure that the study would be useful for them:

- Who in your family would be interested in taking part?
  NB inform parent/carer that if there is more than one child that they would attend different groups, therefore some may have to wait longer

INCLUSION CRITERIA

- Are you (or the parent/carer in question) diagnosed with SMI (psychosis, dual diagnosis, severe depression, personality disorders) Yes/No
- Is your child/children 6-16 years of age? Yes/No
- Is your child/children in contact with the ill parent/carer >10 hrs Yes/No
- Does your child/children have some awareness of the parent's/carer's mental illness Yes/No

Answers to the above must be Yes

EXCLUSION CRITERIA

- Is the child of parents diagnosed with common mental health problems (e.g. mild-moderate depression) Yes/No
- Would your child/children be unable to participate in group work (due to severity of problems, learning difficulties, etc). Yes/No

Answers to the above must be No

It would also be useful to obtain the following information:

- Do you know the name of the person where you heard about the service from?
- What service do they work for?
- Where is this located?

Make a note of this information to save into the Young SMILES spreadsheet

If the family are eligible explain to them the next steps of the study. Ensure that they are aware that there is a 50% chance that they will receive the Young SMILES intervention. If they are not allocated to Young SMILES and to TaU let them know that their care will not be affected and they can still be referred by practitioners to other relevant services and are still able to attend any services/groups that they attend as a family or individually.

Email Contact

If the family has indicated that they only wish to be contacted by email please send the initial screening questions to them in an email and ask if they can be contacted by any other means. The following text can be used and adapted as necessary:

Thank you very much for sending your consent to contact form back to me letting us know of your families interest in the Young SMILES research study. If you are still interested if you would be able to let me know your answers to the following questions check to see if the study would be useful for your family.

If you would prefer that I call you to discuss these if you can reply to this email with a telephone number and let me know when it would be good to contact you that would be great.

- Is your child/children 6-16 years of age? Yes/No
- Are you (or the parent/carer in question) diagnosed with SMI (psychosis, dual
- diagnosis, severe depression, personality disorders) Yes/No
- Is your child/children in contact with the ill parent/carer >10 hrs Yes/No
- Does your child/children have some awareness of the parent's/carer's mental illness Yes/No

- Is the child of parents diagnosed with common mental health problems (e.g. mild-moderate depression) Yes/No
- Would your child/children be unable to participate in group work (due to severity of problems, learning difficulties, etc). Yes/No
-
- Would a parent/carer/significant family member or friend be willing to attend parent Sessions Yes/No

Once I have heard back from you I will be in touch.

If you have any queries whatsoever about the trial at this stage please don't hesitate to ask. I can be contacted by email or phone.

Thanks again and best wishes

Ending the call

Let them know that we need to wait until we have spoken to enough families before the study starts. Inform them that this may be in the next few weeks or may take a little longer. Let them know that you will keep them up to date with progress by contacting them on a fortnightly basis if they would be happy for you to do so. Ask if they would like you to do this by phone or email.

Remind them that when there are enough families you will contact them to arrange to meet with them in their home or preferred community location.

Ensure that they have your contact details (phone/email) if they have any questions in the meantime.

After the initial call

Insert all relevant information into the Young SMILES spreadsheet. Add any information to the *additional information* column that you think would be important to note for the future. This may be regarding family availability or information regarding living situations etc.

Update Phone Call - Checklist

Please tick to confirm you have performed these checks

Family ID -

• Inform family of potential wait	☐
• Provide additional opportunity to discuss trial and ask questions	☐
• Inform family that you will contact them again in 2 weeks or when you will be in the position to book a baseline appointment	☐
• Update Young SMILES family spreadsheet	☐

Booking Baseline Appointment – Checklist

Please tick to confirm you have performed these checks

Family ID –

• Provide additional opportunity to discuss trial and ask questions	☐
• Inform family that there are now enough families interested and that you would like to arrange to meet with them to complete some questionnaires	☐
• Explain purpose/length of baseline appointment	☐
• Confirm location/time of interview	☐
• Provide researcher contact telephone number/email	☐
• Inform family that they will be sent a confirmation letter stating the time and location of the interview (NB inform them that this may not arrive prior to the interview) Young SMILES First appointment letter v1.0 09.03.17	☐
• Input details of baseline interview into spreadsheet	☐
• Inform JG of progress	☐
• Ensure have followed Lone working policy regarding booking interviews e.g. ensure safety contact knows where and when you have arranged appointment	☐

Please note on spreadsheet, if applicable, why all procedures not carried out

Booking Baseline Appointment - Protocol

1. Organising the Baseline Appointment

Advise the family that the interview will last about 1.5 hours (but may be a little longer or slightly shorter) and they will be asked to complete some questionnaires which you will be able to assist them with if needed. Let them know that when you meet with them they will be able to ask you any additional questions that they may have about the study. Also tell them that you will be asking them to complete a form (consent form) at the start of the meeting to confirm that they are happy to take part, let them know though that they can stop taking part at any point.

Interviews will normally take place in the family's home, but they may wish to meet in a different community location. Confirm with the patient their preferred location; you may need to check with the venue if there is a room that you can use. Most community venues or GP surgeries are likely to have a suitable room. Confirm the address and the family's contact details and ensure they have a contact number for you and an available colleague, in case they need to postpone or cancel on the day. You can also pass on my details in case they have difficulty contacting you.

Inform the patient that they will be sent out a confirmation letter with details of the time, date and location of the baseline appointment but if the meeting is soon that this may not arrive before you meet.

Declining participation prior to randomisation

If at any stage during the initial phone call/email contact, they decide they do not want to participate, thank them for their time and record in the Young SMILES spreadsheet that they no longer wish to participate.

Notes Section of Spreadsheet

Please use the additional information column in the spreadsheet for each family to provide information for future reference about issues such as difficulties contacting families (this may be useful when contacting patients at follow-up).

Baseline Appointment - Checklist

Please tick to confirm you have completed these steps

Family ID –

• Family details correct	☐
• Alternative contact details (for family) discussed if required	☐
• Family given opportunity to discuss trial and ask questions Young SMILES Information Booklet Parents-Carers v1.1 31.05.17 Young SMILES Information Booklet 6-11 v1.0 23.03.17 Young SMILES Information Booklet 12-16 v1.1 31.05.17	☐
• Consent obtained and consent/assent forms completed *ensure you insert the ID on the form	☐
• Relevant outcome measures completed by family Book 1 – age 6 Book 2 – age 7 Book 3 – age 8-10 Book 4 – age 11-12 Book 5 – age 13+	☐
• Family informed of next steps	☐
• Give family £20 of vouchers and ask them to sign a receipt Baseline voucher receipt	
AFTER APPOINTMENT:	
• Inform Judith appointment and randomisation	☐
• Enter data into Young SMILES outcome measure spreadsheet	☐
• <u>Newcastle only</u>: contact family to inform them of randomisation outcome	☐
IF FAMILY DECIDES TO WITHDRAW:	
• Thank family for their time and inform them they will continue to receive care as usual	☐
• Inform referrer of withdrawal and add to Young SMILES spreadsheet	☐
• Send family thank you letter following interview Baseline Interview - Pt Thank You	☐

Please note on spreadsheet, if applicable, why all procedures not carried out

Baseline Appointment - Protocol

Before the Interview

Assemble *recruitment interview pack*, consisting of;

- Copy of Information sheets
- Consent forms for all family members (1 for the research team; one for the family)
- Relevant outcome measure booklets for Child and Parent/Carer (dependent on child's age)
- Relevant researcher SOP and checklist
- Distress protocol and sources of support sheet
- Risk protocol
- Adverse events protocol and form
- £20 voucher
- Baseline voucher receipt
- Calling card and envelope (to leave if patient is not in)

Remember to follow your employing institution's lone worker protocol (University or NHS).

Introduction

- Introduce yourself to the family and thank them for agreeing to see you
- Check that the family details on the consent to contact form (name, address, telephone numbers and email address) are correct.
- It is also worth trying to obtain an alternative contact details e.g. email address for the patient (if not already provided).
- Give the family the opportunity to ask any questions. You may need to summarise the study and what is involved again.
- If during the interview, they decide they do not want to participate, thank them for their time and record on the Young SMILES spreadsheet that they no longer wish to participate. Inform Judith of this.

Obtaining consent

- Ask them to sign and date the consent forms – you need to then sign and date them also. Ask each of the family members who will be involved in the trial to complete **two forms** (one for them to keep and one for the research site file). Please ensure you insert their ID number on the consent form.

If the family refuses to consent*:*
Thank them for their time and advise them to continue seeing accessing the services they are currently involved with as normal. Enter information of refusal of consent into the Young SMILES spreadsheet.

If the parent/carer refuses to consent but they are happy for their child to take part:
If a parent/carer does not wish to take part but they are happy for their child to take part then the child can still take part. It would be useful at this stage to identify if there is another family member or friend who could take part in their place.

If the family gives consent then they will complete the relevant Baseline outcome measures (please see Appendix 2 for further details):

Child/young person self-report

1. Demographic questionnaire – young person
2. Pediatric Quality of Life Inventory (PedQol) – child report
3. KIDSCREEN
4. Strengths and Difficulties Questionnaire (SDQ) – child report (if age 11-16)
5. Revised Children's Anxiety and Depression Scale (RCADS) – Child report
6. The Child Health Utility 9D (CHU-9D)
7. Mental Health Literacy Questionnaire (MHLq)

Parent/carer self-report

8. Demographic questionnaire – parent/carer
9. Pediatric Quality of Life Inventory (PedQol) – parent report
10. KIDSCREEN Parent report (if child <8yrs old)
11. Strengths and Difficulties Questionnaire (SDQ) – Parent report
12. Revised Children's Anxiety and Depression Scale (RCADS) - Parent-report
13. Arnold O'Leary Parenting Scale
14. Parenting Stress Index-Short Form (PSI-SF)

Family

15. Child and Adolescent Service Use Schedule (CA-SUS)
    (NB: for collecting data on child resource-use only - if both the child and parent/carer attend an appointment this would count but not if it is only an appointment that the parent/carer attended).

The actual measures that will be completed and who will complete them (child/parent/carer) will be dependent on the age of the child. Booklets for each age relevant age band have been prepared.

End of Baseline Interview

- Give family £20 voucher and ask them to sign voucher receipt. The receipt should be retained in the site file.

- Explain the next steps – randomisation procedure, what happens when allocated to Young SMILES or Treatment as Usual.

- Discuss arrangements for follow-up data appointment(s) and explain what these will involve. Inform them that you will come and see them at 3-monthly intervals over the next year (at 3, 6 and 12 months). It's worth emphasising that the follow-up appointments may be shorter as consent will not need to be obtained.
  Newcastle: Let family know that another researcher will accompany you at the follow-up visits

- Let the family know that you will call them approximately 2-3 weeks prior to when the 3-month appointment is due to arrange.

- Inform them that if they have any queries at any point that they can contact with you or the trial manager (ensure that they have the relevant contact details).
  Manchester: Remind the patient that it is important for you to not know which group they have been allocated to**.**

- Emphasise that the information is equally important to us, whatever group they have been randomised.

- Thank the family for their time. Ensure they have a copy of the consent form and information booklet to keep.

- Following the interview contact JG to inform her it is complete:
  - JG will provide an independent researcher with the ID, site and age band of index child. The researcher will inform her of the allocation (Young SMILES or TaU) via consulting a randomly generated group allocation list prepared by the trial statistician.

- On return to the site office, file a copy of the consent form, permission to contact form and completed checklist, as appropriate. All patient identifiable data must be stored in a lockable filing cabinet, which is locked when not in use, and **never** left unattended.

3. After the Baseline Appointment

Randomisation Procedure

Following the baseline appointment and consent being obtained, families will be randomised on a 1:1 ratio to either Young SMILES or Treatment as Usual.

The randomisation procedure will be centralised and carried out by the Trial Manager (or other UoM researcher if JG is on leave). JG will provide an independent researcher with the ID, site and age band of index child. The researcher will inform her of the allocation (Young SMILES or TaU) via consulting a randomly generated group allocation list prepared by the trial statistician.

- Manchester: JG will contact family directly to let them know to ensure that AK remains blinded.
- Newcastle: JG will inform CC of outcome who will make contact with family to inform them.
- A confirmation letter will also be sent in the post
  Young SMILES Family randomisation letter – Young SMILES v1.0 09.03.17/Young SMILES Family randomisation letter – TAU v1.0 09.03.17
- If allocated to Young SMILES – JG/CC will also inform the referrer and NSPCC/NTW & Barnardo's if allocated to Young SMILES.

1 ***Treatment as Usual*** – the family will continue to receive all the help and support that they are currently receiving from any services they have access to. Practitioners who they see will also be able to refer them to any additional services or support that is available within their locality. Taking part in the trial will not impact on access to anything that is available.

2 ***Young SMILES*** – a practitioner from NSPCC/NTW/Barnardo's will be in touch shortly to arrange an appointment/inform them of the start date and location of the Young SMILES group sessions.
Remind families that Young SMILES involves 8 sessions – the first 4 are for children only and then from 5-8 the parent/carer will be invited to attend parallel sessions. Let them know where sessions will take place (NSPCC Coventry/Warrington Service Centres or Recovery College, Newcastle).

Booking Follow-up Appointment - Checklist

Please tick to confirm you have performed these checks

Family ID -

Approximately 2-3 weeks before a follow-up appointment is due you should contact the family to arrange the follow-up appointment, time and location.

Manchester: From the outset remind the patient that you are to remain BLINDED to the arm of the trial that they have been randomised to.

• Explain purpose/length of follow-up appointment	☐
• Confirm location/time of appointment	☐
• Ensure family have your contact details and also the contact details of the trial manager	☐
• Inform family that they will be sent a confirmation letter stating the time and location of the interview (NB inform them that this may not arrive prior to the interview) Young SMILES Follow-up appointment letter v1.0 09.03.17	☐
• Input details of appointment to Young SMILES spreadsheet	☐
• Send out confirmation letter Young SMILES Follow-up appointment letter v1.0 09.03.17	☐

Approximately 3-4 days prior to the appointment date contact the family to confirm that the date and time is still suitable.

Follow-Up Appointment - Checklist

Please tick to confirm you have completed these steps

Family ID –

• Family details correct	☐
• Alternative contact details (for family) discussed if required	☐
• Family given opportunity to discuss trial and ask questions Young SMILES Information Booklet Parents-Carers v1.1 31.05.17 Young SMILES Information Booklet 6-11 v1.0 23.03.17 Young SMILES Information Booklet 12-16 v1.1 31.05.17	☐
• Relevant outcome measures completed by family Book 1FU – age 6 Book 2FU – age 7 Book 3FU – age 8-10 Book 4FU – age 11-12 Book 5FU – age 13+	☐
• Family informed of next steps e.g. will contact 2-3 weeks before the next follow-up appointment is due to arrange. If this is the last follow-up explain that they will continue to receive support from services etc.	☐
AFTER APPOINTMENT:	
• Enter data into Young SMILES outcome measure spreadsheet	☐
• Inform Judith appointment and randomisation is complete	☐
IF FAMILY DECIDES TO WITHDRAW:	
• Thank family for their time and inform them they will continue to receive care as usual	☐
• Inform referrer of withdrawal and add to Young SMILES spreadsheet	☐
• Send family thank you letter following interview Follow-up interview - Pt Thank You	☐

Please note on spreadsheet, if applicable, why all procedures not carried out

Follow-up Appointment - Protocol

You will have contacted the family approximately 2-3 weeks prior to the follow-up appointment to agree a date and a time. A confirmation letter will also have been sent and you should have made contact with the family a few days before the follow-up appointment to confirm they are still available to meet to avoid wasted visits.

NB it is important to remind them that you need to **remain blinded** to the treatment that they are receiving.

1. Before the Interview

Assemble *recruitment interview pack*, consisting of;

- Copy of Information sheets
- Relevant outcome measure booklet for Child and Parent/Carer (dependent on child's age) – please see Appendix 2
- Relevant researcher SOP and checklist
- Distress protocol and sources of support sheet
- Risk protocol
- Adverse events protocol and form
- Voucher (£10/£20 or £30 dependent on time of study)
- Follow-up voucher receipt
- Calling card and envelope (to leave if patient is not in)

Remember to follow your employing institution's lone worker protocol (University or NHS).

After the interview, thank the patient for their time, and make arrangements for the next scheduled follow-up. If this is the 12 month follow-up interview you can inform the patient that their participation in the trial is now over and thank them for all their help. Inform them that we will be sending them a summary of the results and check that they are happy to receive this.

2. Towards the end of the interview (3-months only)

Qualitative Interview

Whilst detailed in the information sheet for the main trial we would like to ensure that participants are aware that they may be contacted to take part in a qualitative interview about their experiences of the Young SMILES intervention. We would also like to stress at this point that this interview is different to those they have completed so far and that they may or may not be invited to participate in one of these interviews. The following script can be used at the end of the 3-month interview to remind participants of the possibility of this (please note at this point we are not asking for them to indicate if they would like to participate, just informing them):

NB: If you need to remain blinded ensure that the family do not discuss their group allocation at this point

Script for Qualitative Interviews

In addition to the questionnaires we complete with you at the beginning of the study and at 3, 6, and 12 months, we are also interested in finding out families' experiences and what they thought about the Young SMILES intervention.

We will be contacting some families who received Young SMILES to take part in a separate interview to talk about their experiences. These interviews are an opportunity for (children and parents/carers) to let us know what you liked, what you might not have liked so much and if there are things that we could change.

In the near future you may receive a letter in the post, inviting you to take part in this additional study.

3. End of Follow-up Interview

- Give family voucher and ask them to sign voucher receipt. The receipt should be retained in the site file.

- Explain the next steps – when the next follow-up interview will take place or if this is the last one when the study finishes (a summary of the findings will be sent to all families).

- Let the family know that you will call them approximately 2-3 weeks prior to when the follow-up appointment is due to arrange (if applicable).

- Inform them that if they have any queries at any point that they can contact with you or the trial manager (ensure that they have the relevant contact details).
  Manchester: Remind the patient that it is important for you to not know which group they have been allocated to**.**

- Emphasise that the information is equally important to us, whatever group they have been randomised.

- Thank the family for their time. Ensure they have a copy of the consent form and information booklet to keep.

- Following the interview contact JG to inform her know it is complete:

- On return to the site office, file a copy of the consent form, permission to contact form and completed checklist, as appropriate. All patient identifiable data must be stored in a lockable filing cabinet, which is locked when not in use, and **never** left unattended.

Participant Withdrawal Procedures

If at any time during the trial a child, parent/carer, or whole family indicates that they would like to withdraw from the study, it is important to check what they mean by this.

There are three ways which a child, parent/carer, or whole family may wish to withdraw:

1 ***Full withdrawal from trial*** – if they wish to withdraw from the Young SMILES intervention and they are not willing to complete any follow-up appointments. This should be recorded on the spreadsheet and JG should be notified.

2 ***Withdrawal from follow-up*** - this would be appropriate if they wanted to continue with the Young SMILES intervention, to complete any follow-up appointments. This should be recorded on the spreadsheet in the relevant column. This should be recorded on the spreadsheet and JG should be notified.

3 ***Withdrawal from intervention only*** - They may wish to withdraw from taking part in the Young SMILES intervention but are happy to continue to complete any follow-up appointments.
Manchester: to avoid unblinding if JG is informed of intervention withdrawal this will not be recorded on the spreadsheet.

It is important that we maximise the amount of data that is completed by families during the trial, particularly data collected at the 3-month time point (primary outcome point). Therefore it is useful to explore with families if they would be willing to complete any of the measures or if they would prefer more flexibility in the ways that they are completed.

For example, some families may be too busy to complete all of the measures but would be willing to complete some or they don't wish to meet with you in person but would be happy to complete a few measures over the phone. If these circumstances arise the health-related QoL measures at the start of the booklets should be prioritised.

Standard Operating Procedures (SOP) for safeguarding children

1. DEFINITION

For the purposes of this SOP, we use the Department of Health's "Working Together to Safeguard Children" (2013) guidance framework to define "safeguarding":

"the action we take to promote the welfare of children and protect them from harm - is everyone's responsibility. Everyone who comes into contact with children and families has a role to play"

Safeguarding and promoting the welfare of children is defined as:

- Protecting children from maltreatment;
- Preventing impairment of children's health or development;
- Ensuring that children grow up in circumstances consistent with the provision of safe and effective care, and
- Taking action to enable all children to have the best outcomes.

(DH, Working Together to Safeguard Children, 2013: p.5).

2. BACKGROUND

The Children Act, 1989, uses the concept of 'significant harm' as a threshold for determining if abuse is taking place and for intervention. 'Significant harm' is defined as follows under s31 (9) of the Children Act, 1989:

- Harm means ill-treatment or the impairment of health or development, including, for example, impairment suffered from seeing or hearing the ill-treatment of another;
- Development means physical, intellectual, emotional, social or behavioural development;
- Health means physical or mental health, and
- Ill-treatment includes sexual abuse and forms of ill-treatment which are not physical.

The different forms of abuse are defined as follows:

- Physical abuse - involves hitting, shaking, throwing, poisoning, burning or scalding, drowning, suffocating, or otherwise causing physical harm to a child;
- Emotional abuse – involves the persistent emotional maltreatment of a child such as to cause severe and persistent adverse effects on the child's emotional development. It may involve serious bullying, causing children frequently to feel frightened or in danger, or the exploitation or corruption of children. It may also involve seeing or hearing the ill-treatment of another. (Note: some level of emotional abuse is involved in all types of maltreatment of a child, though it may occur alone);
- Sexual abuse - involves forcing or enticing a child or young person to take part in sexual activities. The activities may involve physical contact, including penetrative (e.g. rape) or non-penetrative acts. They may include non-contact activities, such as involving children in looking at, or in the production of, sexual online images, watching sexual activities, or encouraging children to behave in sexually inappropriate ways;
- Neglect -is the persistent failure to meet a child's basic physical and/or psychological needs, likely to result in the serious impairment of the child's health or development. Neglect may occur during pregnancy as a result of maternal substance abuse. Once a child is born, neglect involves a parent/carer failing to:
  - Provide adequate food, clothing and shelter (including exclusion from home or abandonment);

- Protect a child from physical and emotional harm or danger;
- Ensure adequate supervision (including the use of inadequate care-givers);
- Ensure access to appropriate medical care or treatment.

The different indicators of abuse include:

Physical Indicators: injuries which are unexplained or where the explanation is not consistent with the injury; soft tissue injury/bruising; bruising behind the ears; multiple/excess bruising; wariness of adults; inappropriate clothing for the weather; dirty/unkempt/ill-fitting/unchanged clothing; poor hygiene; tired/lethargic; poor/limited language development.

Behavioural Indicators: inappropriate or emotional responses; ambivalent relationship with parental figure; high criticism offered about the child from parent directly to the child or to others; low warmth; absence of affection between the child and his/her carer.

Other Indicators: parent/carer is under the influence of drink/drugs/frequently smells of drink; parent presents as disjointed and uncoordinated/ slurred speech/mentally unwell/drowsy.

It is important to note that there may be other explanations for many of these indicators. This should not preclude taking action to discuss your concerns with Principal Investigator or another nominated clinical contact. It may be that the child and family need support and help for issues other than direct abuse or to prevent abuse occurring or escalating.

3. RESPONSIBILITIES

It is not your role as a researcher to determine absolutely whether a child is suffering from 'significant harm' or not. Your role is to identify and share concerns about a child or children (as described below). Your role should include:

- Awareness of any relevant child protection procedures;
- Recognising indicators of abuse;
- Recording information/monitoring;
- Discussion and/or consultation with an appropriate person (see below);
- Making a referral (if appropriate).

4. RESPONDING TO POSSIBLE MALTREATMENT

Your role in responding to possible maltreatment is not to investigate or to determine if abuse has taken place. These are tasks performed by other professionals directly involved in child protection roles. Your role is to discuss <u>all</u> concerns as soon as possible with the Principal Investigator. This also applies to situations when you may be <u>unclear</u> about potential risks.

5. DISCLOSURE OF ABUSE, HARM OR NEGLECT

Where a participant makes a clear disclosure of abuse, harm or neglect of a child, either perpetrated by themselves or another person, you should:

- Take seriously what the participant is telling you;
- Listen, encourage, but don't ask questions that assume anything;
- Tell the participant that you will need to talk to someone else to decide what to do now and contact the Principal Investigator or one of the nominated clinical persons;
- Seek consent to break confidentiality and disclose this information to their support worker and/or responsible clinician;

- If the participant does not consent to the sharing of this information, it will still be necessary to break confidentiality;
- Check that the participant understands what you are going to do;
- Record their observations and what the participant has said at the earliest appropriate opportunity, including dates and times

6. WITNESSING ABUSE, HARM OR NEGLECT

Where you witness a child being abused, harmed or neglected you should:

- End the interview as soon as possible and immediately inform the Chief Investigator or one of the nominated clinical persons (Clinical site lead) about the situation and discuss what action to take;
- Record what you have witnessed as soon as possible.

Although the above guidance details how to identify possible child protection issues and what to do if you have concerns, there will inevitably be "grey areas". In these instances you should always contact the Principal Investigator or one of the nominated clinical persons, as soon as possible, to discuss what action to take.

Young SMILES Risk Protocol for Assessing and reporting risk in adult participants

The following principles and procedures govern risk assessment and reporting in the Young SMILES study and should be used in conjunction with the *Standard Operating Procedures (SOP) for safeguarding children* (pages 21-23) if applicable. The Young SMILES study does not include routine management of people at acute risk of suicide by trial research assistants. If risk is identified responsibility for managing that risk should be passed to the appropriate healthcare professional or service with the support of a clinically experienced member of the research team.

General procedures

If a participant indicates that they have had thoughts that they would be better off dead or hurting themselves in some way this should be explored using the risk assessment on the following pages.

It is important to note that as the adults involved in the trial are experiencing serious mental health problems that it is likely that they will have had such thoughts at some point. This does not necessarily mean that any action is required in addition to the support that they will already be receiving but it is important to identify if the risk is imminent or not.

Should risk be identified clinically experienced members of the research team will provide support to researchers to ensure that an appropriate decision is made regarding any action required following the identification of risk.

Whenever risk is identified a risk assessment should be completed and counter-signed by the Chief Investigator/clinical site lead as soon after the assessment as possible.

- Any **significant, but not imminent risk** should be reported to the person's GP and to the referring agency/individual and, if appropriate, other health care professionals, as soon as is reasonably possible.

- Any **imminent risk** should lead to the immediate involvement of the appropriate emergency health services. These will vary locally. The Trial Manager and Site Clinical Leads must ensure that researchers are fully informed and competent to follow the procedures.

Young SMILES Risk Assessment - Questions

THOUGHTS

"I see that you've said / you mentioned that……. These are thoughts / feelings that people experiencing mental health difficulties often have, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

PLANS

1 Do you know how you would harm or kill yourself? Yes / No

If **yes –** details

---

2 Have you made any actual plans harm yourself or end your life? Yes / No

If **yes –** details

ACTIONS

3 Have you made any actual preparations to harm or kill yourself? Yes / No

If **yes –** details

---

4 Have you ever attempted to harm of kill yourself in the past? Yes / No

If **yes –** details

PREVENTION

5 Is there anything stopping you killing or harming yourself at the moment? Yes / No

If **yes –** details

---

6 Do you feel that there is any immediate danger that you will harm or kill yourself? Yes / No

If **yes –** details

Young SMILES Risk Assessment - Actions

Actions by Researcher	***Tell Participant***
All answers 'no' apart from Q5 'yes': ↓ **A** ↓ →	*I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) <u>I would advise you to make an appointment to see your GP to talk about these feelings</u>*
'Yes' for any **one** of Qs 1-3; plus 'yes' for Q5 and 'no' for Q6 ↓ **B** ↓ →	*Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. <u>I will be speaking or writing to your GP and to the service/individual who told you about the study to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings.</u>* Inform GP and letter to service/referring individual (within 24 hours) *GP/Service/Referrer Risk Letter v1.0 12.07.17* **NB A participant may be considered actively suicidal and may be excluded. This decision will be made by the site clinical lead.**
Scoring 'no' to Q5 or 'yes' to Q6 ↓ **C** <u>Actively Suicidal</u> ↓ →	*I am very concerned about your safety at this moment. I am not qualified to deal with this on my own as I am not a therapist but I am going to talk to one of the members of the research team who is.* Participant needs immediate help – **do not leave them alone**. Follow the Young SMILES chain of clinical contact and enact immediate risk procedure. **NB a participant may be excluded on the basis of this. This decision will be made by the site clinical lead.**

After taking any of the actions above, fill out *Young SMILES risk form v1.0 12.07.17* and discuss with clinical site lead as soon as possible.

Exploring other risk areas

Other areas of risk which may arise in the interviews may include the following:

- Alcohol and substance abuse
- Risk from others
- Risk to others – this may be addressed in relation to child safeguarding
- Self-neglect

Actions

If any of the above risks are detected by the researcher contact the Chief Investigator/Clinical Site Lead and discuss. Contact details are as follows:

Chief Investigator – Kathryn Abel mobile: 07763 816748

Site Lead (Newcastle) – Lina Gega mobile: 07950 110433

NB: When clinical site leads are away they should ensure appropriate cover is arranged for any risk issues that might arise in their absence.

Following a decision being made about what actions need to be taken:

- The researcher will inform the participants GP and service lead/referring individual. They will also inform the Trial Manager.
- If the participant is currently receiving Young SMILES, the Young SMILES delivery team within the relevant service should also be informed. For participants from Coventry and Warrington sites the Trial Manager will inform the team to avoid unblinding the researcher.

After taking any of the actions above, the *Young SMILES risk form* should be completed, countersigned by the Chief Investigator/ Clinical Site Lead and a copy sent to the Trial Manager.

If risk is identified that is not related to suicide or self-harm then the *Young SMILES Risk for risks not including suicide and self-harm form* ***should be completed*** countersigned by the Chief Investigator/ Clinical Site Lead and a copy sent to the Trial Manager.

The forms associated with the risk protocol/assessment can be found in Appendix 3.

Young SMILES Distress Protocol

If a participant appears to become distressed, the researcher will:

1. Encourage the participant to take a break from completing forms and answering questions.
2. Acknowledge that talking about problems can be distressing.
3. Offer support by reassuring the participant that they do not need to answer a question(s) if they do not wish to
4. Ask if they would like to continue with the interview or prefer to stop.

If they prefer to stop then:

5. Finish the interview and offer to return at another time.
6. If the participant withdraws their consent to participate in the entire study then this should be communicated to the study team.

If the interview continues:

7. Take time at the end of the interview to talk informally, and encourage participants to access further support dependant on their level of distress. This may be to visit their GP or mental health service provider or to access support available from the NSPCC/Childline or other appropriate support services.
8. If the patient has any questions or requires reassurance about the research they should be encouraged to contact the research team, University Research Practice and Governance Coordinator, NSPCC or NHS service(contact details will be provided).
9. If the participant still appears to be distressed when the interview is over offer to phone back in a couple of days to ensure the distress has not escalated and to reiterate the sources of support.
10. If the participant becomes more distressed discontinue interview and identify appropriate support.

Sources of support

If you are experiencing a crisis and require immediate assistance, contact the following organisations and access confidential advice and support via a helpline. Alternatively, please contact your local Mental Health Service, care coordinator or general practitioner.

NSPCC (www.nspcc.org.uk) - The NSPCC works to help children and families of domestic abuse, helping them overcome the effects and restore healthy relationships. NSPCC provides free UK help lines - the NSPCC Helpline and Childline - a free and confidential telephone support service for children andyoung people. Open 24 hours a day.

- ChildLine call 0800 1111
- Help for adults concerned about a child call 0808 800 5000

Samaritans (www.samaritans.org) – The Samaritans offer a confidential listening service for people who are in crisis. They also offer face-to-face meetings in most branches. Call 08457 90 90 90.

SANELINE (www.sane.org.uk) – SANE exists to provide emotional support and information to anyone affected by mental illness between 6:00 pm – 11:00 pm daily. Call 0845 767 8000.

Young Minds (www.youngminds.org.uk) – provides information about emotional wellbeing and mental health for young people.

NHS Direct

0845 46 47 (24 hours every day).

Local Services - Newcastle

Patient Advice and Liaison Service (PALS) - Advice and support to patients, their families and carers, providinginformation on NHS services, listen to concerns, suggestions andqueries regarding your care.
North of Tyne 0800 032 0202 (freephone)
South of Tyne 0800 328 4397 (freephone)

Mental Health Matters A **c**onfidential service offering emotional support. Providesinformation on local and national services specific to mental health.You can talk about bereavement, relationship problems, lonelinessand stress. Also provides support to carers.
Newcastle: 0845 601 2457 (6pm – 6am)
Sunderland: 0800 013 0626 (5pm-9am 24 hours)
Gateshead: 0800 085 1718 (5pm-9am 24 hours)

Newcastle and Gateshead Community Children and Young People's Service
Benton House, 136 Sandyford Road
Newcastle upon Tyne, NE2 1QE
Tel: 0191 246 6913

Northumberland Community Children and Young People's Service
Villa 9, Northgate Hospital, Morpeth
Northumberland NE61 3BP
Tel: 01670 798 265

South Tyneside and Sunderland Community Children and Young People's Service
Monkwearmouth Hospital, Newcastle Road
Sunderland SR5 1NB
Tel: 0191 566 5500

Local Services - Coventry

Coventry & Warwickshire Mind – A mental health service that offers local people living with a mental health problem advice, counselling, and more specialist support. Services open to children, adolescents, and adults.

Wellington Gardens,
Windsor St, Coventry CV1 3BT
Tel: 024 7655 2847

Relate – A confidential support service helping families, children and young people overcome mental health difficulties and relationship problems. Aims to help people understand what is going on in their relationships and change things for the better.

Elliott Court,
Coventry Business Park, Herald Avenue,
Coventry, CV5 6UB
Telephone: 02476 225863

Coventry Children's Service
Logan Centre,
Logan Rd,
Coventry CV2 1AG
Telephone: 024 7678 7980

Local Services – Warrington

Mental Health Matters – A confidential service offering emotional support. Provides information on local and national services specific to mental health. Provides support to carers.
Telephone: 0191 516 3500

St Joseph's Family Centre - Provides a range of family support services unique in their extent, managed by professionally trained staff, counsellors, and volunteers.
Telephone: 01925 635448

Warrington Children's Social Care and Safeguarding Services
Children's safeguarding/social work team
New Town House
Warrington, WA1 2NH
Telephone: 01925 443400

Young SMILES
Adverse Events Reporting SOP

TITLE: Adverse Event Reporting	
VERSION: 1.0	Date: 20.07.2017
Prepared by Dr Judith Gellatly Date: 20.07.2017	Approved by: Prof. Kathryn Abel Date: 26.07.2017
PURPOSE: To describe the process of adverse event reporting and follow-up of adverse events for researchers involved in the Young SMILES feasibility study	

1. PURPOSE

To describe responsibilities and procedures for identifying, collecting, recording and reporting of Serious and Non Serious Adverse Events occurring on the Young SMILES feasibility study.

2. INTRODUCTION

Young SMILES (A community-based intervention to improve health-related quality of life in children and adolescents of parents with serious mental illness (CAPRI): a feasibility study) is sponsored by Manchester Mental Health and Social Care Trust (MMHSCT) and funded by the National Institute for Health Research's Health Technology Assessment (HTA) Programme. An identified member of The Trial Steering Committee (Prof Steven Pryjmachuk) will monitor patient safety within the trial and will be responsible for reviewing any serious adverse events occurring as part of the trial.

3. DEFINITIONS

SERIOUS ADVERSE EVENT – Any untoward medical occurrence that results in one of the following criteria:

- Life threatening (i.e. event in which patient is at risk of death at the time of the event occurring).
- Is fatal (i.e. results in death).
- Requires unplanned or prolonged hospitalisation*.
- Results in persistent or significant disability or incapacity.
- Results in a congenital abnormality or birth defect.
- Any other medical condition not listed above, which may require medical or surgical intervention to prevent the above criteria occurring.

**Unplanned refers to emergency hospitalisations. Prolonged hospitalisation is deemed to be where a patient's stay is longer than expected (e.g. patient is operated on as a day case but remains in hospital overnight).*

NON SERIOUS ADVERSE EVENT – This is any untoward medical occurrence the participant experiences but which does not fulfil any of the serious adverse event criteria.

EVENT OUTCOME - For any adverse event the outcome of the event must be detailed. Events may be:

- **Recovered** – e.g. participant is no longer experiencing any unfavourable symptoms related to the event.
- **Recovered Partially** – Participant is still experiencing some unfavourable symptoms related to the event however the impact of these has improved since the event.
- **Death** – Participant is deceased as a result of the event.
- **Ongoing** – Participant continues to experience unfavourable symptoms which currently remain unresolved.

4. **Young SMILES REPORTING REQUIREMENTS**

This Adverse Event Specific Procedure applies to adverse events in relation to trial participants which occur during the feasibility study and are considered to be related to trial participation.

Events related to any of the following will require reporting as Adverse Events if they are deemed by the Trial Steering Committee member to be related to trial participation and unexpected:

- Any deterioration in mental health condition or wellbeing (i.e., an increase in mental health symptoms) which is perceived to be related to participation in the feasibility study.
- Dissatisfaction with study procedures (i.e., event caused by feasibility study procedures or interaction with feasibility study staff).
- Any unplanned hospital or GP visit for medical conditions which are perceived to be related to participation in the feasibility study.
- Any fatality that occurs during the feasibility study must be reported.

Serious Adverse events that are confirmed by the Trial Steering Committee member to be related to trial participation and are unexpected will be reported to the Research Ethics Committee (REC), Sponsor (MMHSCT) and Funder (NIHR).

PROCEDURE

WHO

1. All Young SMILES research staff who are in contact with patients are responsible for noting adverse events that are reported by the patient and making them known to the Trial Manager (Judith Gellatly) in a timely fashion (as per details below).
2. The Trial Manager is responsible for the processing and reporting of serious and non-serious adverse events in line with the procedure detailed below.
3. The Trial Manager is responsible for ensuring clinician review of the event.
4. The Trial Steering Committee member is responsible for reviewing of Serious Adverse Events (as designated following clinician review by Professor Kathryn Abel or Dr Lina Gega).
5. The Chief Investigator is responsible for signing off all Serious Adverse Events. Any events deemed to be related and unexpected will be reported to the REC, Sponsor and Funder by the Chief Investigator.

HOW

STUDY SITE RESPONSIBILITIES

1. Document details of the event clearly, using the Young SMILES Adverse Events Form. Please ensure that the following are clearly documented:

    - Date of event
    - Action taken – including any treatment and/or medication and dates that this commenced and/or stopped or was changed.
    - Whether the event is deemed to be serious or non-serious (using the criteria as detailed in section 4).

- The outcome of the event.

Please ensure that no patient-identifiable detail is provided on the Adverse Event Form.

2. Events that are **serious** must be reported to the Trial Manager/Chief Investigator **within 48 hours** of YOUNG SMILES staff being made aware of the event.

   Events that are **non-serious** must be reported to the Trial manager **within 5 days** of YOUNG SMILES staff being made aware of the event.

   Reporting of Adverse events should be completed by sending the Adverse Event form to the Trial Manager (judith.l.gellatly@manchester.ac.uk) and Chief investigator if deemed serious (Kathryn.abel@manchester.ac.uk) by email.

   It is the responsibility of the person making the submission to confirm the form has been received and is receiving attention. It is advisable to follow up email submission with telephone confirmation.

3. Study sites should respond promptly to any requests made for further information.

4. Copies of all correspondence and notes relating to an adverse event should be retained in the Trial Master File on site at the University of Manchester and in the site file where the event occurs at a site other than Manchester. Reasons for late reporting must be documented on the SAE report form and in the Trial Master and site files.

   CHIEF INVESTIGATOR/TRIAL MANAGER/CLINICIAN RESPONSIBILITIES
   Upon receipt of completed adverse event form(s), the form will be processed as described below:
   i. The adverse event form will be reviewed by the Trial Manager.
   ii. In the event that this is deemed to be 'serious', the second opinion from the Chief Investigator will be sought.
   iii. In the event that the Chief Investigator confirms the event to be 'Serious', this will be provided to the Trial Steering Committee member for review who may seek the advice of other members of the Trial Steering Committee if required.
   iv. All correspondence about the adverse event will be saved and held securely in the Young SMILES Master File.
   v. Should a site provide identifiable details on any adverse event form, this will be destroyed upon receipt. Staff will be contacted to inform them of this breach of Data Protection and the need to destroy any copy that they have and to recomplete and resend the Adverse Event form removing any participant identifiable information.
   vi. Those Serious Adverse events that are confirmed by the Trial Steering Committee to be related to the research and are unexpected will be reported to the Research Ethics Committee (REC), Sponsor (MMHSCT) and Funder (NIHR) by the Chief Investigator **within 15 days.**

BEFORE SENDING AN ADVERSE EVENT TO THE YOUNG SMILES TRIAL MANAGER/CHIEF INVESTIGATOR PLEASE CHECK:

- Is the form fully completed?
- Has any patient identifiable information (e.g. name, address) been included on the form?

Young SMILES ADVERSE EVENT REPORTING GUIDELINES

Is the event serious?

	STUDY SITE	**YOUNG SMILES CHIEF INVESTIGATOR/ TRIAL MANAGER**	**YOUNG SMILES STEERING COMMITTEE (TSC)**	**Young SMILES CI/TM**
	Site to report to Young SMILES CI/PM within:	TM/CI to review. Where confirmed as serious, CI/TM to report to Trial Steering Committee member:	TSC to review serious adverse event on receipt	If event is related and unexpected CI/TM to report to REC, Sponsor and Funder
SERIOUS	48 hours of being made aware of the event.	Within 48 hours of receipt.	TSC committee member to determine if event is related AND unexpected. Chair to inform TM/CI of decision within 5 days of receipt.	Within 15 days.

Is the event non-serious?

	STUDY SITE	**YOUNG SMILES TRIAL MANAGER**
	Site to report to Young SMILES TM within:	Trial Manager to report to TSC:
NON-SERIOUS	5 days of being made aware of the event.	To be reported at next scheduled meeting

YOUNG SMILES – SITE ADVERSE EVENT REPORTING FLOWCHART

Study site receives notification that Young SMILES participant has experienced an adverse event.

EVENT IS SERIOUS

- Results in death.
- Is life threatening.
- Requires unplanned or prolonged hospitalisation.
- Results in persistent or significant disability or incapacity.
- Is a congenital anomaly or birth defect.
- Any other medical condition requiring medical or surgical intervention to prevent the above.

Adverse Event form to be completed, clearly documenting all necessary information.

Please ensure that no patient identifiable detail is provided on the Adverse Event Form.

Event to be reported to Young SMILES TM/CI within 48 hours of the site being made aware of the event. The form should be submitted via email and receipt confirmed.

Young SMILES TM/CI/TSC

SAEs to be processed within 48 hours of receipt of notification.

All SAEs deemed to be related and unexpected (following CI AND TM review) to be sent to the TSC within 48 hours of receipt for review and assessment.

TSC to inform CI/PM of decision within 5 days of receipt.

CHIEF INVESTIGATOR

All related **and** unexpected SAEs to be notified to REC, Sponsor and Funder within 15 days of initial receipt.

EVENT IS NON SERIOUS

Event does not fulfil 'Serious' criteria.

Adverse Event form to be completed, clearly documenting all necessary information.

Please ensure that no patient identifiable detail is provided on the Adverse Event Form.

Event to be reported to Young SMILES TM within 5 days of the site being made aware of the event.

The Adverse Event form should be submitted via email and receipt confirmed.

Adverse Events Contacts

Young SMILES Trial Manager
Dr Judith Gellatly
Tel: 0161 306 7672
Email: judith.l.gellatly@manchester.ac.uk

Participant Trial ID | | | | |

Date of onset of event | | | | | | |
day *month* *year*

How were you notified of the event? **Date notified:**

FULL description of the event: *(including any current medication)*

The local research team deem this event to be: **SERIOUS** ☐ **Non-Serious** ☐

Classification if SERIOUS:
Death ☐ Persistent or significant disability/incapacity ☐ Hospitalisation required/prolonged ☐
Is a congenital anomaly or birth defect ☐ Is life threatening ☐ Other medically important condition ☐

Please state outcome of event at time of this report

Recovered fully ☐
Recovered partially ☐
Died ☐
Ongoing ☐

Date recovered / died

Day	*Month*	*Year*

Name

Signature

Date | | | | | | |

Telephone Number

Researcher Blinding Protocol

Risks to blinding

Researchers are at risk of being unblinded via several channels and points in the Young SMILES study:

- from the participants
- from discussions with clinical staff at sites

Communication with Participants & Clinical staff

Accidental unblinding through communication with participants and clinical staff is a significant risk. The most likely is in discussions with participants at follow-up interviews or during contact between interviews.

Table 1 – Communication of blinding

Time point	Who, what, when
Introducing the Young SMILES study to clinical teams within Trusts	- Although the majority of this will be done by the CI/site lead and trial manager there may be times where you contact the clinical site. In such circumstances: o Explain the RCT and the importance of the blinding process to staff o Explain that the you should not know if the participants have been randomised to the control or intervention group o If any of the clinical staff at the site have any queries please direct them to the Site Lead/Trial Manager or CI who will not be blinded
Initial phone call/Baseline Appointment	- Explain the randomisation and blinding process to the participants as part of consent process - Emphasise to the participant that they should try to remember not to talk to you about the intervention should they receive it - Remind them that if they have any queries about the intervention they have been allocated to that they can discuss these with the Trial Manager or Young SMILES facilitators (if allocated to the intervention group)
Follow-up Appointment	- A fortnight before the follow-up assessment is due, contact the family to arrange the follow-up interview (as per follow-up appointment protocols). Remind them at this point that you are to remain blinded. - Remind participant at beginning of all contacts to not discuss their allocation

If you are unblinded please complete the form on the following page.

Researcher Follow-up Appointment Unblinding Report Form

Please complete this form to indicate if you have been unblinded at any point during the trial

Name of RA: _____

Site: _____

Participant ID: _____

Unblinding Time point: 3month 6month 12month

Other: _____

If unblinded at a follow-up appointment please complete the following questions:

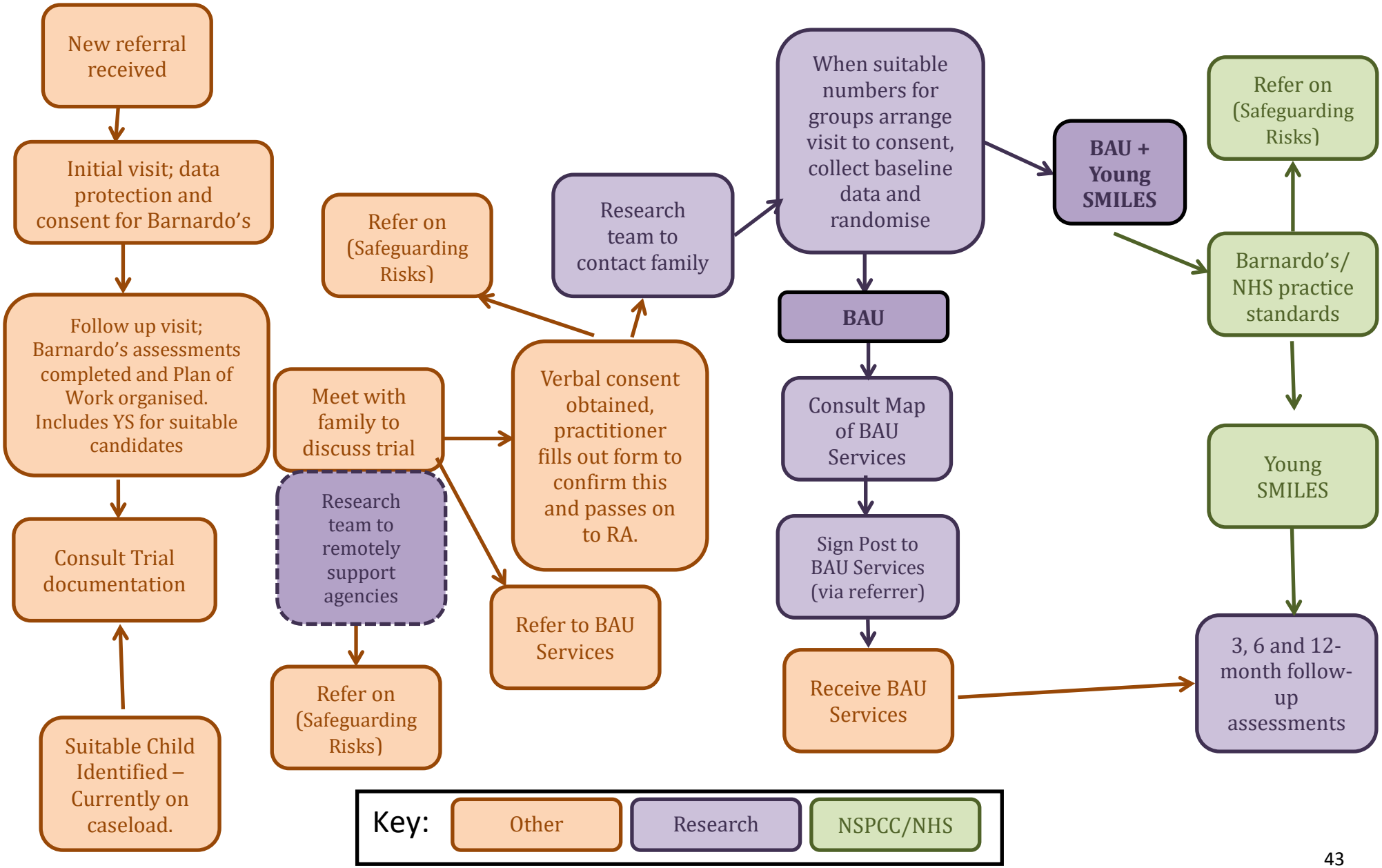
1. Point at which this occurred: At the start at the end during the appointment

2. Measure being completed at the time: _____

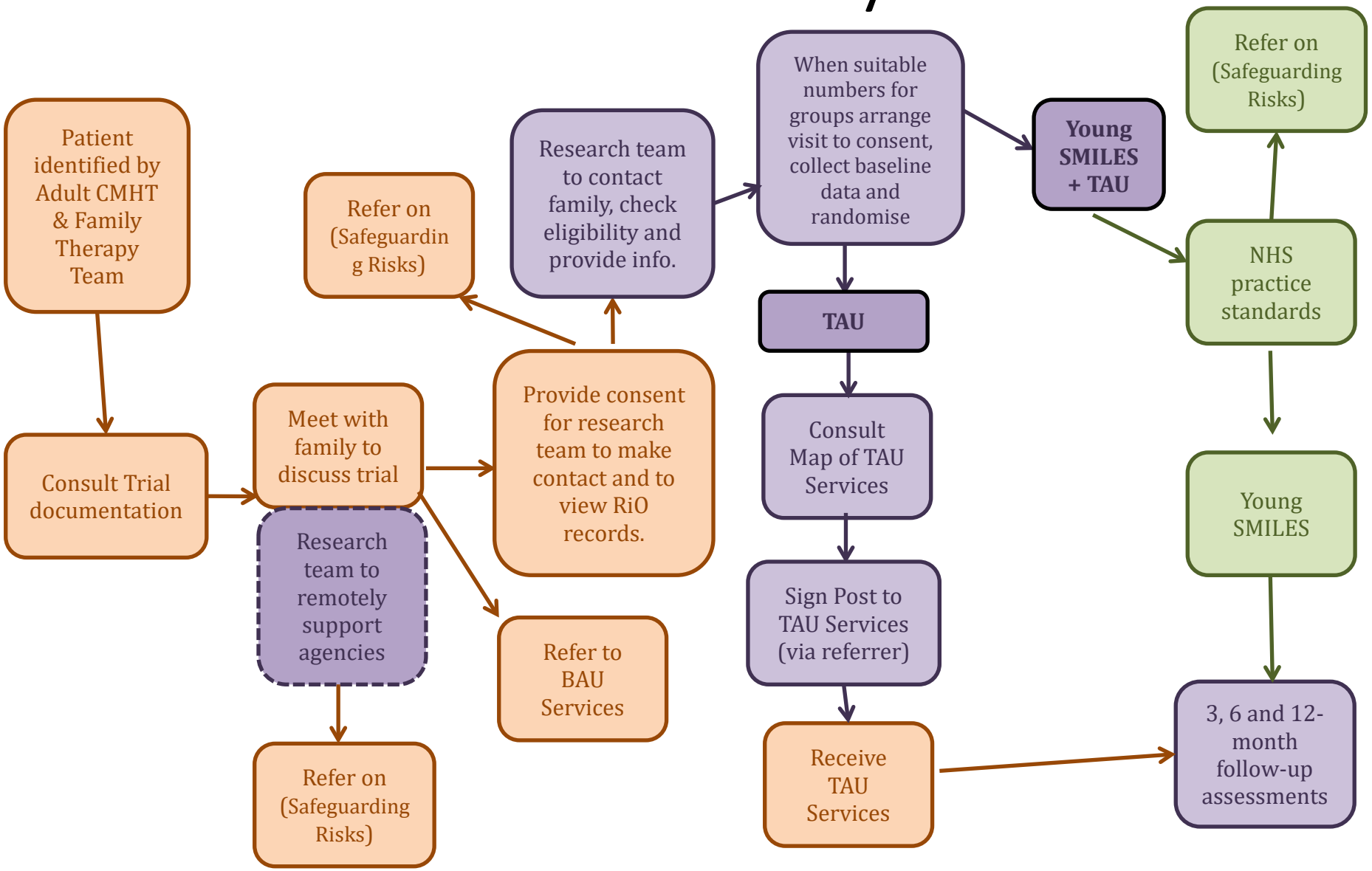
Appendix 1
Recruitment Pathways

1. Barnardo's Newcastle
2. Northumberland Tyne & Wear NHS Foundation Trust
3. NSPCC - Coventry & Warrington

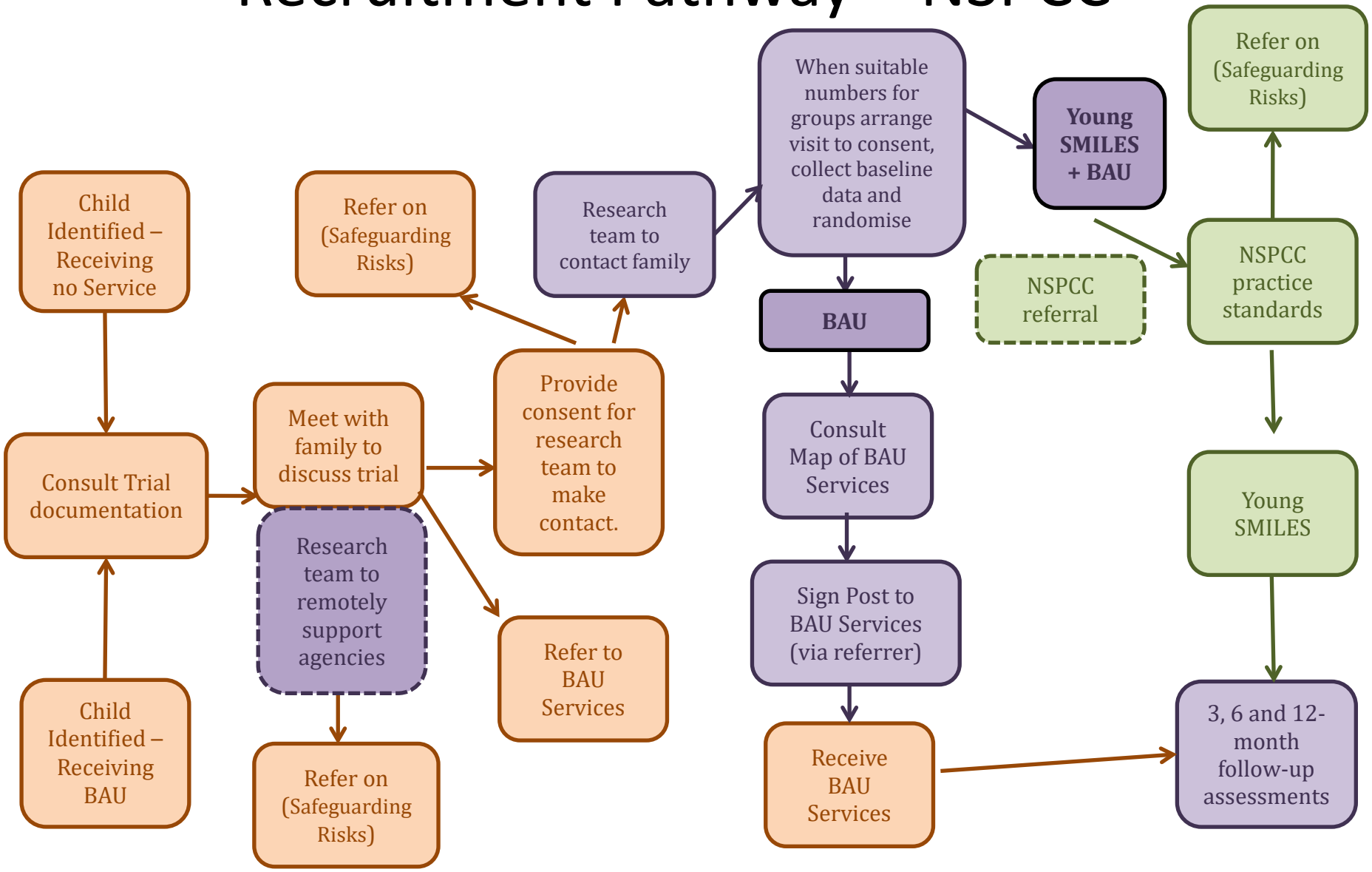
Recruitment Pathway – Barnardo's



Recruitment Pathway – NTW



Recruitment Pathway – NSPCC



Appendix 2

Outcome Measure Booklet Overview

	Age	Initial Assessment	Follow-up Assessment	Completed By	
		Psychometric		**YP**	**Parent/Carer**
BOOK 1	**Age 6**	Demographic (Young Person)		x	
		PedQol (5-7)		x	
		CHU-9D (with support)		x	
		MHLq (with support)		x	
		Demographic (Parent/Carer)			x
		PedQol (Parent Report 5-7)			x
		KIDSCREEN-52 (Parent report)			x
		SDQ parent Report (Initial)	SDQ parent report (follow-up)		x
		RCADS-25 (Parent Report)			x
		Arnold O'Leary Parenting Scale			x
		Parenting Stress Index			x
		CA-SUS		x	x
BOOK 2	**Age 7**	Demographic (Young Person)		x	
		PedQol (5-7)		x	
		CHU-9D		x	
		MHLq (with support)		x	
		Demographic (Parent/Carer)			x
		PedQol (Parent Report 5-7)			x
		KIDSCREEN-52 (Parent report)			x
		SDQ Parent Report (Initial)	SDQ parent report (follow-up)		x
		RCADS-25 (Parent report)			x
		Arnold O'Leary Parenting Scale			x
		Parenting Stress Index			x
		CA-SUS		x	x
BOOK 3	**Age 8-10**	Demographic (Young Person)		x	
		PedQol (8-12)		x	
		KIDSCREEN		x	
		CHU-9D		x	
		RCADS-25 (Child Report)		x	
		MHLq (with support)		x	
		Demographic (Parent/Carer)			x
		PedQol (Parent Report 8-12)			x
		KIDSCREEN-52 (Parent report)			x
		SDQ Parent Report (Initial)	SDQ parent report (follow-up)		x
		RCADS (Parent Report)			x
		Arnold O'Leary Parenting Scale			x
		Parenting Stress Index			x
		CA-SUS		x	x

BOOK 4	**Age 11-12**	Demographic (Young Person)		x	
		PedQol (8-12)		x	
		KIDSCREEN		x	
		SDQ (Child Report)	SDQ child report (follow-up)	x	
		RCADS (Child Report)		x	
		CHU-9D		x	
		MHLq		x	
		Demographic (Parent/Carer)			x
		PedQol (Parent Report 8-12)			x
		KIDSCREEN-52 (Parent report)			x
		SDQ (Parent Report)			x
		RCADS Parent Report (Initial)			x
		Arnold O'Leary Parenting Scale			x
		Parenting Stress Index			x
		CA-SUS		x	x
BOOK 5	**Age 13+**	Demographic (Young Person)		x	
		PedQol (13-18)		x	
		KIDSCREEN		x	
		SDQ (Child Report)	SDQ child report (follow-up)	x	
		RCADS (Child Report)		x	
		CHU-9D		x	
		MHLq		x	
		Demographic (Parent/Carer)			x
		PedQol (Parent Report 13-18)			x
		KIDSCREEN-52 (Parent report)			x
		SDQ Parent Report (Initial)			x
		RCADS (Parent Report)			x
		Arnold O'Leary Parenting Scale			x
		Parenting Stress Index			x
		CA-SUS		x	x

Appendix 3
Risk Protocol Forms & Letters

1. Young SMILES suicide risk and self-harm form
2. Young SMILES Risk for risks not including suicide and self-harm form
3. GP/Service/Referrer Risk Letter

Young SMILES suicide risk and self-harm form v1.0 12.07.17

Young SMILES ID: …… SITE: ……

Date participant seen: ……

Assessed risk as A B or C
Copy of 'Young SMILES Risk Assessment – Questions' attached

Outcome of this assessment:

Chief Investigator/Clinical lead contacted Y / N Date ……

Instructions given:
[This should include contacting GP by telephone and follow-up letter and contacting the service lead/referrer who informed the family of the trial. The Trial Manger will contact the service lead/referrer in the sites covered by the Manchester team]

Actions taken

……	…….	……
Researcher Name	Signed	Date
……	…….	……
Clinical Site Lead Name	Signed	Date

Young SMILES Risk for risks not including suicide and self-harm form v1.0 12.07.17

Young SMILES ID: …… SITE: ……

Date participant seen: ……

Risk identified:……

Outcome of this assessment:

Clinical lead contacted Y / N Date ……

Instructions given:
[This should include contacting GP by telephone and follow-up letter and contacting the service lead/referrer who informed the family of the trial. The Trial Manger will contact the service lead/referrer in the sites covered by the Manchester team]

Actions taken

……	…….	……
Researcher Name	Signed	Date
……	…….	……
Clinical Site Lead Name	Signed	Date

GP/Service/Referrer Risk Letter v1.0 12.07.17

Surgery Address

Date

Dear Dr _____

Re: [Participant Name] _____

As you may be aware, [PATIENT NAME], is taking part in a research trial led by The University of Manchester – *Community-based intervention to improve health-related quality of life in children and adolescents of parents with serious mental illness: feasibility study (Young SMILES)*. As part of this research I meet with [him/her] on a number of occasions with their [child/ren] to complete measures exploring their children's quality of life. I am writing to update you about our meeting today.

During the appointment today [PATIENT NAME] indicated thoughts that they had *"Thoughts that you would be better off dead or of hurting yourself in some way"*

As a result of this I carried out a further risk assessment as per the trial protocol and determined that whilst I do not believe [PATIENT NAME] to be in immediate danger, I feel they would benefit from talking to you about these thoughts.
I have recommended that they arrange to make an appointment to come and see you to discuss this further.

OR

They are experiencing significant difficulties and the risk assessment identified immediate risk to themselves and/or others.
The following action was taken as a result…….

It is part of our study protocol to inform you of such risks, so that you can take account of them in your care plan.

Yours sincerely,

[Site Researcher]