Research Ethics Approval

13 October 2022

Professor Dame Carolyn Hamilton, DBE
Director, Coram International
Community Campus
41 Brunswick Square
London WC1N 1AZ, United Kingdom

RE: Ethics Review Board findings for: *Formative and Summative Evaluation of the Childcare and Deinstitutionalisation Reforms in seven countries in Europe and Central Asia 2009 – 2022* (HML IRB Review #629ECAR22)

Dear Dame Carolyn Hamilton,

Protocols for the protection of human subjects in the above study were assessed through a research ethics review by HML Institutional Review Board (IRB) on 29 September – 13 October 2022. This study's human subjects' protection protocols, as stated in the materials submitted, received **ethics review approval.**

You and your project staff remain responsible for ensuring compliance with HML IRB's determinations. Those responsibilities include, but are not limited to:

- ensuring prompt reporting to HML IRB of proposed changes in this study's design, risks, consent, or other human protection protocols and providing copies of any revised materials;
- conducting the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to mitigate hazards to subjects;
- promptly reporting any unanticipated problems involving risks to subjects or others in the course of this study;
- notifying HML IRB when your study is completed.

HML IRB is authorized by the United States Department of Health and Human Services, Office of Human Research Protections (IRB #1211, IORG #850, FWA #1102).

Sincerely,

D. Michael Anderson, Ph.D., MPH
Chair & Human Subjects Protections Director, HML IRB

cc: Saltanat Rasulova, Penelope Lantz, JD

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HML Ethics Review Board

Research Ethics Review Document

Review of UNICEF Research Project Materials for the Protection of Human Subjects

This document serves to meet UNICEF ethical standards for research, evaluation, data collection and analysis, and is the official record of an ethics review. It is designed to ensure effective processes and accountability for ethical oversight and to ensure the protection of, and respect for, child and adult rights within all research, evaluation, and data collection processes undertaken or commissioned by UNICEF. It conforms with the UNICEF Procedure for Ethical Standards in Research, Evaluation, Data Collection and Analysis; Document Number: CF/PD/DRP/2015-001; Effective Date: 01 April 2015, Issued by Director, Division of Data, Research and Policy.

The Purpose of Research Ethics Review

The purpose of an Ethics Review Board (ERB) or Institutional Review Board (IRB) is the protection of human research subjects' rights. These rights include *Respect* for individuals to make free decisions, *Justice or equity* regarding distribution of the burdens and benefits of research, and *Beneficence* or the obligation to do good and avoid harm.

ERBs review research protocols that involve the collection and analysis of data from human subjects to ensure that ethical standards are upheld. This is to protect the rights and welfare of subjects and to ensure that:

- subjects know the purpose of the study and are not placed at undue risk;
- participation is voluntary and confidential;
- subjects are provided and agree to informed consent prior to their participation;
- relevant protocols are in place to assure subjects' protection and safety, and;
- data collection and analysis does not result in the violation of privacy or discrimination.

Before issuing approval, the ERB must determine that the following requirements are satisfied:

- informed consent is sought from each subject or the subject's legally authorized representative;
- the proposed research design is scientifically sound and that risks to subjects are minimized;
- any risks to subjects are reasonable in relation to anticipated benefits;
- subject selection is equitable;
- safeguards are included for subjects likely to be vulnerable to undue influence or coercion;
- subjects' safety, privacy, and confidentiality are maximized.

Materials Requested for Review:	**Also, please include:**
1. Inception Report / Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, subject recruitment, subject protection and data protection plans. 2. Copies of all Informed Consent documents. 3. Copies of all data collection instruments.	4. Written protocols to ensure subjects' safety.* 5. Written protocols for the protection of human subjects' identities.* 6. Written protocols for the protection of data.* 7. Other relevant documents. *These may be statements incorporated into research plans and/or embedded in a single protection protocol. .

HML IRB is an autonomous committee authorized by the United States Department of Health and Human Services, Office for Human Research Protections (IRB #1211, FWA #1102, IORG #850), to review and approve research involving human subjects before the start of research, and to conduct annual reviews of that research independent of affiliation with the research organization submitting materials for review.

Please submit your materials in English for review to:
D. Michael Anderson, PhD, MPH, HML IRB Chair & Human Subjects Protections Director
and Penelope A. Lantz, JD, HML IRB General Counsel
unicef@hmlirb.com

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UNICEF Research Ethics Review for Human Subjects' Protections

→ INVESTIGATORS: Please confirm your project information and any additional information requested below.

Project Title:	***Formative and Summative Evaluation of the Childcare and Deinstitutionalisation Reforms in seven countries in Europe and Central Asia 2009 – 2022***
HML IRB Research Ethics Review ID#:	629ECAR22
Initiating UNICEF Official: Name, CO, & RO	Saltanat Rasulova srasulova@unicef.org
Principal Investigator/Project Manager: Name, degree(s), organization, & address	Professor Dame Carolyn Hamilton, DBE Director, Coram International
Other Key Personnel: Names & titles	**International child protection and research experts:** Awaz Raoof, Elizabeth Yarrow, Amelia Smith, Bruce Grant **National researchers:** Hasmik Tamamyan (Armenia), Miglena Baldzhieva (Bulgaria), Sopio Khozrevanidze (Georgia), Aleksandra Gligorovic (Montenegro), Ines Cerovic (Serbia), Nevenka Zegarac (Serbia), Zarringul Alimshoeva (Tajikistan) **Research officers:** Rosalie Lord and Catherine Burke **Project management and research support:** Adam Cunliffe
Contracting Firm: Name & address	Coram International Community Campus 41 Brunswick Square London WC1N 1AZ, United Kingdom
Primary study site(s): (e.g., country, province, region)	Armenia, Bulgaria, Georgia, Montenegro, Serbia, Tajikistan
Project duration: (Dates from -- to)	August 2022 – July 2023

Duration of Subjects' Participation: (Dates from -- to)	November 2022 – January 2023
Thematic Area/Areas:	Child Protection Social Policy Human Rights
Target population:	Children with disabilities and other difficult to place children.

Date of ERB Request	29 September 2022
Date(s) ERB Comments Returned	05 October 2022
Date Final Documents Received	12 October 2022
DATE OF ERB APPROVAL	13 October 2022

UNICEF Ethics Review Process

HML Ethics Review Board (UNICEF LTAS 42107154) will conduct a research ethics review of submitted materials and make comments below under **Additional Information Needed**. We will then return this template for responses from investigators.

Please respond to our comments in another colour, directly under each comment.

- Please provide any requested or revised materials, and please note where revisions to your materials may be found by page or paragraph number.
- Please do not alter ERB comments or the format of this document.

This HML ERB review document serves as the official record of the ethics review for the project named below. This document, including all comments and responses, will be retained by UNICEF and HML ERB as a record of this review. Once you and we have agreed on the ethical rights of your research subjects, we will issue a letter of approval.

	Ethics Review Board Criteria of Interest	Additional Information Needed → Investigators: Please respond to ERB info requests in another color directly below the request	X or NA equal PASS (for ERB use)
Section 1	***ERB Submission:*** **Are all requested project information, materials, and final documents provided separately or incorporated in text? This includes:**		
1.1	Inception Report or Research Protocol, containing, e.g.,: specific aims or objectives, research questions, study design, analysis & dissemination plans	Please keep us informed of any subject protection protocol or research design changes that need to occur in adaptation to the COVID-19 pandemic in the sites of your study. Have updated the ethical protocol in Annex E to include information on this in more detail.	X
1.2	Informed Consent documents	Please provide ICs for group interviews. Please see Annex H with participant information sheets. These can be used for group and individual interviews.	X
1.3	Surveys and data collection instruments	Please provide the data collection tool for onsite observations. Removed observations from methodology. Please provide the interview guide for interviews with children and caregivers together. Removed heading and from MN participant list. We will not be interviewing children and caregivers together. Please provide the data collection tools for follow up interviews with the institution, child's social worker, and other connected professionals. Have added specific tool, please see Annex K. P.151 of the Annexes is a child interview guide with notes that say it can be adapted for group interviews.	X

		We need to see all final data collection tools. Please provide all FGD guides for all ages of children and adults and all interview guides for all ages of children and adults.
		We have data collection tools in Annex K for:
		• UNICEF
		• National level Government officials
		  ○ Ministry of Labour and Social Welfare
		  ○ Ministry responsible for child protection
		  ○ Ministry responsible for education
		• Community Service staff
		• Children's residential institutions
		• NGOs
		• Interviews with children in care (separate tool for 7-9 year olds, 10-12 year olds, 13-18 year old's)
		• Interviews with parents of children with disabilities
		
		In the Annexes on p.47 you state that to mitigate the risk of retraumatizing children: "*participants will not be asked directly to share their harmful experiences*." However, on p.152 on the child interview guide questions 5 to 11 ask specifics about the situation that led the child to be in care. Please consider revising.
		Whilst difficult, this is an essential question for the evaluators to understand as it helps us to assess the reasons why children are in care, potential barriers for them returning to the family, challenges which may lead to difficulty placing this particular child in alternative care. It is also important to hear from children about their experiences, and their understanding of their own care experience. All researchers are trained in interviewing children who have experienced trauma, and will take a trauma informed approach to asking this question by:	

		• Reminding children that they are free to not answer the question if they do not want to, and that they can have a break; • Not probing for a detailed answer. From our experience children will most likely respond with a short/one word description of why they have been placed in care (i.e. poverty, parental death); • Asking this question mid-way through the interview, to ensure that some kind of rapport has already been built with the researchers and there if sufficient time for the child to go back to 'easier' and emotionally safer questions further on in the interview; • Most frequently we will pose this question in an individual interview setting, and rarely in a group interview unless the group consists of two or three children who are very comfortable with each other and happy to talk about this; and • Supporting children by signposting to relevant services and providing contact details of the team leader on the participant information sheet. In Annex K on p.122 you provide a list of data collection tools. However, three are missing. They are: National level Government officials, Residential Homes, and Interviews with parents of children in care. Please provide. All tools are now up to date and provided (please see Annex K).	
1.4	Written protocols to ensure subjects' safety		X
1.5	Written protocols for protection of subjects' identities		X
1.6	Written protocols for protection of data		X
1.7	Other relevant documents		X
1.8	Do protocols include a section identifying ethical issues and measures to mitigate ethical problems as required		X

	by *UNICEF Procedure for Ethical Standards*? Included		
1.9	Have informed consent and data collection instruments been pre-tested?	Please respond. No, this is not possible given time considerations. However, all tools have been validated by UNICEF country offices and will be tested by national and international researchers in the field at the start of data collection and revised where necessary.	**X**
1.10	Are all submitted documents final versions?	Please respond. The version you received was not the final version of the data collection tools. Please find the final up to date version now attached in Annex K.	**X**
1.11	May the final protocol and instruments be included in an internal UNICEF searchable database for colleagues to learn from your work?	Please respond: INCLUDE or OMIT. OMIT.	**X**
1.12	Additional comments or suggestions	Please confirm that this submission is solely for review and approval of the study components to be conducted in Montenegro and the other five countries will be reviewed separately. This ethical review is for all six countries covered by the study, but there may need to be contextual amendments needed to suit the settings in individual countries. The substantive methodology and data collection tools will not change. Please provide interview questionnaire for parents of children in care. Provided. See Annex K.	**X**
Section 2	***Research Design:*** **Do submitted materials describe the proposed research? This includes:**		
2.1	Is the study's background, rationale, and study design scientifically sound?		**X**
2.2	Does study involve intervention, treatment, comparison, or control groups?		**X**

2.3	Type of data collection: a. survey questionnaire……..……..….. b. subject interview (+IDIs) ……..……..X c. key informant interview (KII)……..……..X d. focus group discussion (FGD)……..……..X e. document (desk) review……..……X f. on-site observation…… g. case study…….. h. analysis of secondary data…….. i. physical measurements …….. j. biological specimen ……..…… k. other……..	In Appendix I you include several site observations but provide no description of what these involve. Please describe what observations include and revise your protocols to include them as part of data collection and research methodology. Have removed these from Annex I. Why in some cases interview the child with the caregiver? Have removed. In several places in the research protocol and in the instructions included with interview guides you mention making decisions about when and how to conduct individual verses group interviews. You also provide an interview/FGD schedule for Montenegro as Annex I. We are assuming that you will follow the data collection protocol in Annex I. Is that a correct assumption? Yes, we will follow the protocol in Annex I. This was included as it is recognized based on our teams experience interviewing children in care that in some situations (especially in group homes for children) children may feel more comfortable on the day interviewing with their peers in a group format. The tools have been developed with this in mind.	
2.4	Number of Data Collections: a. one-time (no follow-up) …… b. two or more (follow-up) ……		X
2.5	Sample size: Approximate total *n* = 90 – 160	About 20 – 30 KIIs in each country + about 12 FGDs/IDIs in each country + about 6 – 10 interviews per country + 7 observational visits listed for Montenegro, correct?	X

		In each country we propose, 20-30 KIIs, 8-12 FGDs/IDIs with children, 6-10 interviews. We have removed observational visits for MN. Will there be 7 observational visits in each of the other countries as well? No. We have removed these. Please provide the estimated total sample size = Estimated total sample size = 34 – 52 KIIs/FGDs per country. Assuming 8-10 people are involved per FGD and interviews are all individual, this would mean approximately 90 – 160 participants.	
2.6	Are any subjects children (<18 years old)? 7 – 17 yo	What are the ages child subjects? Aged 7-18 years old. The data collection tools have been developed with this in mind.	X
2.7	Additional comments or suggestions		X
Section 3	***Subject Risks:*** **Are risks reasonable in relation to any benefits to subjects and to the importance of knowledge that may be expected to result from the research?**		
3.1	Is the research *Minimal Risk* Only?: This means the probability and magnitude of anticipated harm or discomfort is no greater than ordinarily encountered in daily life or during performance of routine physical or psychological exams or tests.		X
3.2	Does the research involve *greater than minimal risk*, but where risks are justified by anticipated benefits; where the relation of the anticipated benefits to risks is at least as favorable as available alternative approaches; and where the intervention or procedure is likely to yield generalizable knowledge? If so, are mitigating procedures described?		X
3.3	Do study objectives show that risks are reasonable in		X

	relationship to expected gains and benefits are clearly articulated?		
3.4	By their participation, are subjects vulnerable to any of the following?: a. physical risk …….. b. psychological risk …….... c. social risk ……..……. d. economic risk ……... e. legal risk ……..……..... f. political risk ……..…….. g. employment risk…… h. academic risk…….... i. religious risk……..…. j. other……	Are children in potential risk of physical or social harm for disclosing negative things about their facility in a group interview? Yes, this is likely. Steps will however be taken to mitigate this risk. Have added this to the list of potential harms in the ethical protocol (Annex E).	**X**
3.5	In event of any of the above risks, do protocols describe clear strategies to mitigate risks?	Please describe risks for children in group discussions, both from being overheard by nonparticipants and from other participants sharing what was said outside the group. Have added this to the list of potential harms in the ethical protocol (Annex E).	**X**
3.6	Does the study request information or opinions where public disclosure may result in danger, limitations to future freedoms, or access to services?		**X**
3.7	Do gender, ethnicity, or other demographic characteristics -- or grouping of subjects by any of these characteristics, especially in FGDs -- increase subject risk?	You indicate that you may hold group interviews instead of KIIs. Please explain under what conditions you would use group interviews and where you would use KIIs. Based on our teams experience interviewing children in care that in some situations (especially in group homes for children) children may feel more comfortable on the day interviewing with their peers in a group format. Please see point 6.4 in Inception Report for an explanation. You further state that you will not "*to the extent possible"* interview subordinate workers with the	**X**

		senior colleagues due to employment risks. Given that you acknowledge employment risks, why would you ever conduct a group interview where this dynamic and potential for risk existed? Acknowledge this as an issue. Have changed this in the methodology to ensure that subordinate workers are not interviewed with the senior colleagues (See page 29 of Inception Report).	
3.8	If a subject discloses or is suspected to be at risk outside the study, are procedures in place to address or report risk and refer subject for relevant support?	P.47 of the Annexes states: "*Additionally, when interviewing children and young people with experience of the care system, children may experience re-traumatisation … For those that do choose to share their experiences support will be made available, and participants will be signposted to appropriate services using the information sheet*." What information sheet and what additional services are available to children already in custodial care? The Participant information sheet in Annex H sets out ways children can receive support if they require it. We will signpost children to the national helpline and provide them with the contact details of the Team Leader, Professor Dame Carolyn Hamilton, who will be able to liaise with UNICEF to provide additional support services if required. What about resources/support for parents of children? Have created a separate participant information sheet for parents which signpost's parents to a national mental health helpline and provides them with the contact details of the Team Leader, Professor Dame Carolyn Hamilton, who will be able to liaise with UNICEF to provide additional support services if required. According to the protocol (Annex G) "*Reporting will take place when all of the following three conditions (a, b, and*	**X**

		c) are satisfied: a) The issue concerns a new case, i.e. a case/child that is not already known to a child protection agency; and b) The threshold of harm has to be high, i.e. significant harm; and c) The abuse is ongoing or highly likely to occur, such that the child is suffering or is likely to suffer significant harm*." In this evaluation, all child respondents are already in some form of child protection and therefore by definition not a new case. Does this mean that there will be no reporting of children at risk? Please explain and modify the protocol if needed. As the children being interviewed as part of this study do not meet requirement a (i.e. they are existing cases) they would not meet the reporting threshold and would therefore not be reported. This is because the harm the children experienced is the reason for their placement in the care system, and this is already known to the authorities.	
3.9	Is local reporting abuse of minors mandatory? If yes, has consideration been given to the impacts and consequences of mandatory reporting?	On p.150 of the Annexes you ask children ages 7 to 9 in a group setting if anyone ever hits them. What actions must be taken if a child says yes? This question has now been removed. But more broadly, if a child discloses experiencing violence in the residential institution we will report if the conditions for reporting are met: (*a) The issue concerns a new case, i.e. a case/child that is not already known to a child protection agency; and* *b) The threshold of harm has to be high, i.e. significant harm*; and* *c) The abuse is ongoing or highly likely to occur, such that the child is suffering or is likely to suffer significant harm* This is in line with the protocol outlined in Annex G.	**X**

3.10	Additional comments or suggestions		X
Section 4	***High Risk:* When subjects are vulnerable to heightened risk have additional safeguards been included to protect their rights and welfare?**		
4.1	Can subjects be perceived as vulnerable, including: children, especially unaccompanied or separated (UASC); lacking WASH, food, shelter, or medical care; refugees in conflict or post conflict; those in natural, ecological, or disaster settings; mothers & pregnant women; forced migrants and illegal or undocumented immigrants; prisoners or persons in institutions including orphanages or juvenile justice systems; gang members; those with mental or physical illness or disability; those with HIV/AIDS; those at economic or educational disadvantage; persecuted minority groups, or under high familial, peer, or social pressure? If yes, are study-specific protection protocols provided?		X
4.2	Does the sampling strategy target people at risk for issues such as: violence, torture, abuse, kidnapping; sexual exploitation, harassment, prostitution or pornography, female genital mutilation, reproductive or sexual issues; sexual orientation; child, early or forced marriage; suicide? If yes, are study-specific protection protocols provided?		X
4.3	Are subjects involved in any of the following: slavery, including the sale and trafficking of children; forced labour, servitude, forced recruitment to armed groups; war or armed conflict; illegal activities, production or trafficking of drugs; economic exploitation; work that could damage health or safety; removal of organs for exploitation? If yes, are study-specific protection protocols provided?		X
4.4	Does the study request information relating to illegal activities? If yes, is an MOU in place with government to ensure that no participant is prosecuted? Have participants been notified of this agreement?		X

4.5	Additional comments or suggestions		X
Section 5	***Recruitment:* Do submitted materials describe subjects and the recruitment process?**		
5.1	To what extent are subjects identified: a. names are recorded with responses…… b. names recorded separate from responses…..X c. no names are recorded ..…… d. other personally identifiable information (PII) is recorded……X e. no PII is recorded …… f. subjects are given a unique identifier..... g. other……		X
5.2	If subject name or any other PII is recorded, are procedures included for how this info will be kept separate from responses?		X
5.3	Are subject recruitment procedures & sampling strategy adequately described?	Please describe how child subjects are selected and recruited. Children are sampled purposively in line with the methodology from the children's homes/resource centres in each of the research locations. They will be selected by researchers on arrival in the homes, with consideration given to ensure participants are a mix of genders, ages, ethnicities. What safeguards will there be for ensuring that institutional caretakers do not know which children actually participated? It is not possible to implement safeguards here. However, all respondents will be pseudo-anonymized. You stated that you would conduct additional interviews with social workers and some children. How will these children be selected? Children are sampled purposively in line with the methodology from the children's homes/resource centres in each of the research locations. They will be selected	X

		by researchers on arrival in the homes, with consideration given to ensure participants are a mix of genders, ages, ethnicities.	
5.4	Do recruitment procedures clearly describe ways and means to ensure privacy of subjects throughout the recruitment process?		**X**
5.5	If subjects are children or other vulnerable groups, are materials (e.g.: survey instruments, focus group topics, etc.) age appropriate?	Please provide age-appropriate data collection tools for all ages of child subjects. Noted. Have added data collection tools for children aged 10-12 years old and children aged 13-18 years old, in addition to the existing tool for children aged 7-9 years old. Please note that focus groups should not include discussions of personal information that may be upsetting to a child. For instance, on p.150 of the Annexes you ask children ages 7 to 9 in a group setting if anyone ever hits them. Please consider revising. Have amended tools.	**X**
5.6	If subjects are children or other vulnerable groups, or if subject matter is sensitive, is recruitment sensitive to subjects' potential vulnerabilities (real or perceived) and does it ensure privacy throughout recruitment?	On p.39 you state, "*where a child remains in institutional care, a follow up interview will be conducted with the institution and the child's social worker. ... In addition, other connected professionals will be interviewed where relevant. This will depend on each case but may include a CSO / NGO or other service providers, a school or health care professionals etc*." In these cases, will the child in care also be interviewed? Linking in-depth interviews with professionals to children in care potentially poses privacy and confidentiality risks. Please justify. Yes, we will be interviewing the social worker and he child. However, these interviews will be focused on the child's entry into care, and transition from care and their understanding of it. Please see tool in Annex K.	**X**

5.7	Do recruitment procedures show indication of bribery, coercion, intimidation, compulsion, pressure, or force?	Since facilities will know which children are selected and participate or refuse, how do you avoid children feeling coerced? Comprehensive informed consent procedures are used at the start of each interview. All participants are given a participant information sheet at the start of the interview (see Annex H) which reminds them that they do not have to participate if they choose not to, that they can stop the interview or not answer certain questions at any time without any repercussions. This will be done in a room without an adult from the facility present, to ensure the child's confidentiality. We will introduce ourselves to children from the outset and build a rapport to ensure the child feels comfortable in the setting. If the child is unhappy or withdraws consent we will not continue. The institution will be reminded on arrival that only children who consent to being interviewed will be able to participate and that it is the decision of the child themselves, not the institution or parents/guardians. Coram International's ethical guidelines for field research (Annex C) explain this in greater detail.	X
5.8	Is recruitment of some members of the population and not others likely to result in resentment for either inclusion or exclusion? Have strategies to address this been adequately described?	Please describe. This is unlikely to be the case. However, to mitigate this occurring researchers will ensure group interviews with children in residential care are as inclusive as possible (children can opt in to participating). Given that there is no material benefit to children of participating it is unlikely their decision to not participate will result in any negative consequences/resentment.	X

5.9	Are potential subjects likely to conflate participation with potential or actual goods or service provision? Have strategies to address this been adequately described?	Please describe. This is unlikely. The participant information sheet (Annex H) clearly states that participants will not receive any compensation or changes in their circumstances as a result of participating. This sheet will be given to all participants at the start of the interview, and explained to them in age-appropriate language.	X
5.10	If subjects are paid, compensated, provided a gift, or provided other benefits or services for participation, is the incentive described and justified as non-coercive?	No compensation, correct? Yes. No compensation is provided. This is made clear to participants in the participant information sheet (Annex H) which will be given to all participants at the start of the interview, and explained to them in age-appropriate language.	X
5.11	Additional comments or suggestions		X
Section 6	***Informed Consent:*** **IC is a negotiation whereby subjects are informed about the study and their rights, and they agree to participate voluntarily. IC must be sought from each subject or the subject's authorized representative confirming this process.**		
6.1	Type of Informed Consent: a. written & signed ……..……X b. written not signed ……. c. written & signed by authorized representative.... d. written with online checkbox……..…… e. verbal & signed or recorded…….. f. verbal & signed by authorized representative…. g. verbal not signed or recorded……..……. h. active…… i. passive…….. j. other ……..…		X
6.2	Are the processes for obtaining each IC adequately described?	Please describe for onsite observations. Removed this method.	X

		Please provide the consent forms for group interviews. Consent forms are provided in Annex H. These will be the same forms for group interviews for FGDs as for individual interviews. Each individual should complete a separate form.	
6.3	Does the IC include a clear and simple invitation to participate, an explanation of what the subject will be expected to do, and why they are being recruited?		X
6.4	Does IC include the purpose of the research presented in simple, age, education, and culturally appropriate local language?	Child assent form may not be age-appropriate for youngest children. Please revise. Have created a second version of the consent form for younger children.	X
6.5	Does IC state that participation is voluntary, and subject may choose to not respond to any or all questions, or may withdraw anytime without consequences?		X
6.6	Does IC include the expected duration of the subject's participation (hours/minutes)?		X
6.7	Are subjects given a clear indication of who will have access to their responses and in what form?		X
6.8	Are subjects given a clear description of potential re-use or sharing of data, with whom, and in what form?		X
6.9	Does IC include a description of any risks or benefits to subjects?		X
6.10	Does IC include a statement describing how confidentiality (or anonymity) will be maintained, and if there are any limitations to confidentiality?		X
6.11	Does IC provide identity and contact info of investigators? Is the form of contact useful and appropriate given power dynamics and access to resources like phones or email?		X
6.12	For child subjects, is IC being obtained from parent, guardian, caregiver, or authorized representative? If not, is a justification provided for why this is unnecessary?	Please describe who is providing consent for subjects under 18 and when and how this consent is obtained. Consent for children under 18 in residential care will be provided by the residential institution. Children will also	X

		independently be able to consent at the start of the interview, as explained above and in our ethical guidelines (see Annex C). Please provide the text to be used to obtain parental/caregiver consent and please have a place for them to provide a signature. Have added a box for parent/guardian signature in the consent form in Annex H. When will you obtain consent from the child and his parent or guardian? Will obtain consent from institution, as above. This will take place prior to interview.	
6.13	For child subjects, is their role in the study described adequately and in an age and culturally appropriate manner for them to provide written or verbal *assent*?	You have a written child consent and you have some assent language at the start of the interview guide. Please explain how you will use both and why not have a single one? There is no consent information at the start of this version of the data collection tools. Researchers will only use the process contained in Annex H, explaining the information sheet to children and asking them to complete the consent form. Please describe when and how you will obtain child assent. In all interviews/FGDs involving children.	**X**
6.14	Do IC materials advise subjects to keep focus group discussions (FGD) confidential from anyone outside the group?	Please include in ICs for FGDs.. We will use the same informed consent form as used for the KIIs for FGDs.	**X**
6.15	Where subjects differ by type (e.g.: age, sex, risk, status, etc.), are IC documents specific for each type?	What is your plan if a respondent does not want to be audio recorded?	**X**

		Researchers will take detailed hand-written notes instead. These will be stored anonymously with identifying characteristics removed.	
6.16	Where data collection differs by method (e.g.: survey, FGD, interview, audio recording), do ICs cover each method?	Please provide ICs for each type of data collection: interviews, KIIs, FGD, and observations. We do not feel a separate informed consent sheet is necessary for each data collection method. Instead, the one contained in Annex H will be used both for FGDs and KIIs. OK	**X**
6.17	If IC is written, is a copy left with subjects or there is explanation for not doing so?	Will you leave a copy of the IC with each subject and parent or guardian? If not, why not? We will leave the participant information sheet with each participant.	**X**
6.18	Additional comments or suggestions		**X**
Section 7	***Subject Protections:*** **Do submitted materials clearly identify protection against risk?**		
7.1	Do materials describe protocols for subjects' safety throughout data collection, analysis, storage, and dissemination?	Where will FGDs take place to ensure that no one at the facility or anyone else can overhear? FGDs will take place in a separate room within the facility. It is suggested to use a conference/meeting room, classroom or similar where there is a door that can be closed to ensure sound does not travel and conversations cannot be overheard. Staff of the institution will not be invited to sit in on these FGDs. Will children be interviewed by same or different sex interviewers? All children will be interviewed by female researchers.	**X**
7.2	Are all data collected necessary for the purposes of evidence generation?		**X**
7.3	Do data analysis and reporting procedures ensure subject confidentiality (or anonymity) and security?		**X**

7.4	If future contact with subjects is planned, does it provide for confidentiality and data security through the research period and beyond?		X
7.5	If children or other vulnerable groups are subjects, have personnel had experience working with these groups? If not, what specialized instruction will they receive?		X
7.6	Have personnel collecting data from subjects had ethical training specific to the target group?		X
7.7	Are personnel collecting data aware of ethical issues that may arise and provided mitigation strategies?		X
7.8	Additional comments or suggestions	Who are the translators and where are they from? Will any of them be from the facilities/homes where the children reside? Translators used will be national researchers who are independent of the children's homes.	X
Section 8	***Data Protections:*** **Do data collection and storage protocols adequately ensure subject & data safety?**		
8.1	Are data collection tools appropriate and constructed to assure subject confidentiality or anonymity?		X
8.2	Do data collection procedures and environment ensure data security?	It appears that program data (p.37) may include identifiable beneficiary records. Please clarify. If individual records will be searched and analyzed, please include procedures for de-identifying the records and protecting individuals' privacy. Yes, records may be accessed and reviewed by the Coram team who are trained researchers. Where individual records are accessed by the team with the permission of the institution, researchers will be sure to pseudo-anonymize any notes taken relating to children's cases, and to remove identifying information (i.e. location of child, name of children's home, gender). In general, information of this nature will not be published by the researchers (i.e. there is no intention to conduct case studies), however, having a broad understanding of the overarching issues in a variety of children's cases	X

		will help inform the researchers understanding of the functioning of the care system. Similarly, please describe prior survey data sets and whether they have already been de-identified. If not already de-identified, please include procedures for de-identifying them prior to analysis. All secondary data being used by the researchers has already been de-identified.	
8.3	Do procedures cover all data types (e.g., written, audio, video, observation), and are protections described for each type?	Please describe for paper ICs. All paper informed consent documents will be shredded in country once it has been confirmed and noted for the record that all participants, translators, researchers and parents/caregiver have signed the consent forms.	**X**
8.4	If data will be shared with partners, is there a clear agreement or NDA?	No data sharing, correct? Yes, no qualitative data will be shared.	**X**
8.5	Do protocols describe chain of custody of data and protections for data transfer or transmission, storage, de-identification, and destruction?	Why store audio recordings, transcripts, and data for seven years? We recommend three years. This time limit is in line with UK GDPR requirements. All information on the Coram Groups detailed Data Protection Policy can be found in Annex F.	**X**
8.6	Additional comments or suggestions		**X**

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IRB Change in Protocols Request

WHEN TO REQUEST A CHANGE OR PROTOCOL FOR A STUDY APPROVED BY HML IRB

Any proposed change to the IRB protocol or consent form(s) must be reviewed and approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate hazard to the participant. Please complete this form **and submit any relevant documents** to request a change in protocols. In the event we determine that changes are substantial and require re-review, we will contact you.

RESEARCH PROJECT INFORMATION

Project Title:
Formative and Summative Evaluation of the Childcare and Deinstitutionalisation Reforms in seven countries in Europe and Central Asia 2009 – 2022.

IRB Project ID Assigned by HML IRB: **629ECAR22**

Principal Investigator (PI): **Professor Dame Carolyn Hamilton**

PI Phone #: **+447930347304** PI Email Address: **Carolyn.Hamilton@coramclc.org.uk**

IRB Approval Date: **13 October 2022**

Provide a description (and attach documentation) of the current process, procedure, tool or consent that is being changed:

An additional study site, Moldova, will be included in the evaluation and the project duration is now expected to end December 2023. Procedures, tools and consent protocols will all remain the same.

Provide a description of the proposed change(s) and any revised materials showing the proposed changes:

The inception report, tools, consent forms and information sheets are generic for all countries. The research schedule specific to Moldova will be formulated following the completion of an evaluability assessment.

Reason/Justification for request of change in protocols:

More funding has become available allowing for an expansion to the scope of the research.

Please answer yes or no to the questions below. If you answer yes, provide a detailed explanation in a separate document.

1. Is the change in protocols in response to an unanticipated adverse event? **No**
2. Is the change in protocols in response to complaints by subjects about the research? **No**

HML IRB INTERNAL USE ONLY:

Date Received: 24 Jan 2023 Date Processed: 26 Jan 2023 Date Change Approved: 14 Mar 2023

ANY OTHER ACTIONS TAKEN: ADDITION OF MOLDOVA AS A STUDY SITE USING EXISTING DATA COLLECTION TOOLS AND INFORMED CONSENTS IS REVIEWED AN APPROVED.