ANNEX E: ETHICAL PROTOCOL AND CRITERIA FOR ETHICAL REVIEW CHECKLIST

The research project will be carried out in compliance with UNICEF's *Procedure on Ethical Standards in Research, Evaluation, Data Collection and Analysis* (2021),[1] UNICEF's *Ethics Charter and Guidance for Ethical Research Involving Children,*[2] Coram International's *Ethical Guidelines for Field Research with Children* and recent guidance relating to data collection during Covid-19.[3] Please see Annex B for Coram International's Code of Conduct for field research, and Annex G for Coram International's Protocol for referring cases of significant harm identified during data collection.

This ethical protocol will be submitted alongside the Inception Report, data collection tools and a detailed letter outlining the scope of the study to UNICEF's LTA holder for ethical reviews, Health Media Labs. The UNICEF Europe and Central Asia Regional Office (ECARO) will help to facilitate this submission.

This protocol sets out how these Guidelines will be applied in the context of this evaluation.

1.1 Harm/Benefit Analysis

A fundamental principle of ethical research with human participants is 'do no harm'. This means that the welfare and best interests of participants are the primary considerations guiding the design of the methodology and data collection methods.

UNICEF's and Coram International's ethical guidelines require a consideration of whether the research needs to be done, if children need to be involved in it, and, if so, in what capacity. An analysis of potential harms of the research on children and other participants, is required, along with an assessment of the benefits of the research. Strategies are required to ensure that children are not harmed as a result of their participation in the research, and that distress due to their participation is minimised.

Benefit analysis

It is important to establish that the research will bring benefit to children and their communities more generally and that it is necessary (the research process will bring about *new* information or knowledge).

The justification and rationale for the research is set out in the study's inception report. The evaluation will assess the strengths and weaknesses in approaches taken by different countries, provide insight

[1] UNICEF., UNICEF Procedure on Ethical Standards in Research, Evaluation, Data Collection and Analysis, 2021. Available: https://gdc.unicef.org/resource/unicef-procedure-ethical-standards-research-evaluation-data-collection-and-analysis, accessed 23 September 2022.
[2] Graham, A., Powell, M., Taylor, N., Anderson, D. and Fitzgerald, R. *Ethical research involving children* (2013), UNICEF Innocenti: Florence.
[3] Berman, G., *Ethical considerations for evidence generation involving children on the COVID-19 pandemic*, 2020, UNICEF Innocenti, Florence. ; The Market Research Society, *MRS Post-Covid-19 lockdown guidance: undertaking safe face-to-face data collection*, 14 July 2020.

on how to address possible system level bottlenecks and assess the results achieved by governments and UNICEF to date (outcome and impact level) in supporting children with disabilities and other highly marginalized and vulnerable children in the regions to remain with families or in family-based care. The evaluation will provide an important learning opportunity, both for UNICEF and its partners, especially governments, and will draw attention to experience and evidence on policies and good practices, which in turn will inform UNICEF's future childcare and deinstitutionalisation programming.

In order to strengthen child care reform and deinstitutionalisation efforts in the region and support the development of alternative care, prevention and transition services for looked after children, it is important to produce robust evidence on progress made to date. This evaluation is therefore crucial in providing the evidence needed to inform the ongoing deinstitutionalisation efforts in Europe and Central Asia.

The research will involve primary qualitative data collection, including key informant interviews, in-depth/group interviews with children and parents and in-depth/group interviews with service providers and frontline workers. Primary data collection will be conducted in Sofia, Montana, and Stara Zagora, Bulgaria. The research will also collect and analyse existing data that provides insight on the childcare reform efforts nationally. This will include evaluability assessments, literature made available by Bulgaria UNICEF Country Office, existing raw and collated administrative data held by UNICEF and the Governments of the respective countries, service user databases, reports, and other data records for tracking cases, data collected by the national statistics agencies, survey datasets (e.g. MICS and DHS), policy and legislation, programme reports, work-plans, monitoring frameworks, existing evaluations, monitoring financial reports, and other documentation of relevance, such as broader assessments of alternative care and child protection systems and studies on the situation of, or assessments of support for children with disabilities.

Harm analysis

Front-line professionals and service providers could face negative repercussions should it be discovered that they have expressed views that are considered to be negative or exemplify challenges in supporting children in, or when leaving, institutional care. However, this risk will be mitigated through a thorough informed consent process, reminding participants they are free to withdraw from interviews or not answer questions, and through following strict anonymity and data protection protocols (see below).

Children also may face some negative consequences if they were to disclose negative experiences of the institution during their interview. However, this risk will be mitigated as children will not be asked directly about their experiences, additionally, interviews with children will take place in closed rooms and individuals from institutions will not be invited to observe or join interviews. Informed consent processes at the start of each interview will also remind children that they are free to not answer questions. Institutions will be reminedd that the purpose of the study is not to critique individual institutions, but rather to learn lessons from progress taken to deinstitutionalise nationally.

Additionally, when interviewing children and young people with experience of the care system, children may experience re-traumatisation if sharing specific experiences of violence, abuse and

neglect or their experiences of living in institutional care more broadly. To mitigate this risk participants will not be asked directly to share their harmful experiences. 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.

Harm minimisation strategies

It is important to ensure that all necessary measures are taken to minimise physical and emotional harm to participants and to researchers. The following strategies will be used to minimise harm and ensure the meaningful participation of front-line service providers, professionals and Government representatives in the research.

Selection and training of researchers

All researchers have necessary qualifications, knowledge and considerable experience carrying out data collection with professionals, government representatives, children, and service providers, including on sensitive topics. The national research consultants have been recruited on the basis of their knowledge or experience of the child protection systems in place in Bulgaria and their extensive research experience.

International researchers have all undergone criminal history checks and all researchers, including the national researchers, are required to sign a code of conduct as part of the contracting process.

Researchers will all be involved in an orientation session prior to the pre-testing of tools and data collection. This will be led by the Coram International team and will cover the purpose and aims of the research, ensuring familiarity with the data collection tools and training on the ethical protocol and tools.

Pre-testing tools

The data collection tools will be piloted by international and national researchers on a small sample of research participants, in order to test the understanding and utility of the tools and their cultural appropriateness, allowing for tools to be adjusted before data collection commences.

Recruitment of research participants

Researchers will need to ensure that recruitment of participants does not increase the risk of them suffering from harm. Front-line professionals at the sub-national level will be selected on the basis of them having an existing role in relation to the protection and support of children in institutional care and associated services, and will therefore already be known to the community in this capacity.

Design of data collection tools and data collection approaches and processes

The topics that may be covered in the research may cause reputational concern to some participants (i.e. when discussing challenges in deinstitutionalising children from their care facility). Throughout

interviews, researchers will be sensitive to this and remind participants that they may withdraw consent from the interview at any time and that they are not obligated to answer questions if they feel uncomfortable doing so. Data collection tools have been designed in a manner that avoids direct, confronting questions, judgement and blame. They have also been developed to ensure that they are relevant to the cultural context. Pre-testing these tools will ensure that they are relevant and appropriate and that they avoid confronting or culturally insensitive questions. These matters will be covered in-depth during the orientation session with the researchers.

Ensuring the safety of participants and researchers

It is currently expected that interviews will be conducted in-person. Covid-19 restrictions in each of the six research countries remain in flux and are regularly monitored by the Coram International team. Key informant interviews and group interviews will be conducted at professionals places of work, but researchers will request use of a private room where possible to ensure confidentiality. When interviewing children special attention will be paid to ensuring that children feel comfortable, the space is appropriate to the age of the child and that children are provided with practical and emotional support where needed.

Throughout the research, the Covid-19 situation will be continually monitored, and if the research is considered to put participants or researchers at risk, interviews will be conducted via Phone / Zoom / WhatsApp / Skype etc. If required, for remote KIIs researchers will communicate with participants to ensure that they are in a private location during the virtual interview. However, where preferable for participants, interviews maybe carried out where participants are located in their households. All data collection will take place in daylight hours.

All interviews will take place in classrooms or meeting rooms which have a door that can be closed to reduce the risk of non participants overhearing interviews. Additionally, staff of the institution will be asked not to join interviews, and will be reminded that the purpose of the interview is not to conduct research on the living standards in the institution or other potentially sensistive topics, but rather to understand the borader national picture on deinstitutionalisation since 2009.

Children will be asked not to share in detail what happens within the group and will be reminded that what they say will be stored securely and only shared in a pseudo-anonmyzed format.

Coram International will take measures to support the mental wellbeing of researchers. Coram has a Mental Health First Aid focal point within its staff and researchers will be provided with the opportunity to de-brief with the manager of the research project or member of staff responsible for supervising data collection. Researchers will be sign-posted to counselling services if required.

Responding to trauma, distress and protection disclosures

It is unlikely, although possible, that adult participants disclose past or current traumatic experiences. In these cases, it is essential that participants provide consent to any protection referrals. On request, by emailing the team leader, participants will be given a list of service providers that they are able to

contact to receive support or assistance. All children will be given the phone number of a child helpline as part of the information sheet provided at the beginning of each interview.

1.2 Informed consent and voluntary participation

Researchers will ensure that participation in research is on a voluntary basis. Researchers will explain to participants in clear language that participants are not *required* to participate in the study, and that they may stop participating in the research at any time. Researchers will carefully explain that refusal to participate will not result in any negative consequences. Incentives will not be provided to participants in order to ensure that participation in the research has not been induced). Participants will be clearly advised that their participation or lack of participation in the study will not lead to any direct benefits or sanctions / removal of benefits.

All research participants will be required to give positive informed consent in order to participate in the study. Researchers will use participant information sheets (Annex H) in all interviews and will obtain verbal consent, which will be recorded; however, consent forms will not be used. Consent forms will not be used as formal consent forms may be intimidating to children and other individuals who are not used to the process, and may hinder discussions in interviews. Consent will be verbally requested and interviewers will make a note of whether consent has or has not been given in notes.

At the start of each interview, research participants will be informed of the purpose and nature of the study, their contribution, and how the data collected from them will be used in the study. The research will explain, in clear, age appropriate language, the nature of the study, the participant's expected contribution and the fact that participation is entirely voluntary.

If unsure, researchers will request the participant to relay the key information back to them to ensure that they have understood it. Participants will also be advised that the information they provide will be held in strict confidence (see below).

In addition to seeking consent from individual participants, it is important to seek the support of the relevant Government Ministries / Departments, NGOs and institutions or care facilities where children are living. The letters will explain the purpose and nature of the study and the purpose of the data collection, and requests assistance in accessing research participants.

1.3 Anonymity and data protection

The identity of all research participants will be kept confidential throughout the process of data collection as well as in the analysis and writing up study findings. The following measures will be used to ensure anonymity:

- Interviews will take place either in person in a secure, private location (where possible, in a room within a service provider's office / government office etc.) which ensures that the participant's answers are not overheard;

- Researchers will not record the name of participants and will ensure that names are not recorded on any documents containing collected data, including on transcripts of interviews;
- Researchers will delete electronic records of data from laptops immediately after they are sent to Coram International (in a password-protected and secure Dropbox account);
- Coram International will store all data on a secure, locked server, to which persons who are not employed by the Centre cannot gain access. All employees of Coram International, including volunteers and interns, receive a criminal record check before employment commences;
- Transcripts will be saved on the secure server for a period of seven years and will then be deleted; and
- Research findings will be presented in such a way so as to ensure that individuals are not able to be identified.

All participants will be informed of their rights to anonymity and confidentiality throughout the research process, verbally and in information sheets. All efforts will be made to avoid gathering information that may result in a compromise to participant confidentiality; in any cases where this is not possible, participants will be informed. This may occur where, in a particular, named setting, the background information relating to a participant may make it possible for them to be identified even where they are not named. Researchers will then ask participants whether they wish to have this information removed from any published report of findings (e.g., location, specific job title etc.). However, the interview topics are not particularly sensitive as they will not relate to specific incidents or cases and will focus on generalised issues facing children in the care system. The physical or professional risks to participants are therefore minimal.

It is noted that interview transcripts will be typed or hand written in real time. Audio recording will not be used as this could be intimidating and may lead to participants feeling unable to communicate freely and provide more authentic information.

1.4 COVID-19 situation

The national and international research teams will comply with all national and local laws related to the prevention of the spread of Covid-19. All international researchers are fully vaccinated against Covid-19 and are able and willing to present these credentials upon arrival in the research locations should these be required.

The Coram International project management team will closely monitor the Covid-19 situation in advance of data collection commencing, and will consider possible restrictions when developing the individualised risk assessment for each field mission. In particular the team will monitor the global World Health Organisation Covid-19 dashboard, as well as the following website for information in Bulgaria:

- UK Foreign and Commonwealth Office Advice on Foreign Travel to Bulgaria;

All researchers will be encouraged to follow all relevant guidance on COVID-19 safety, including the wearing of masks, social distancing and personal hygiene.

Coram International has a mandatory plan for protection against COVID-19 during face-to-face data collection should transmission rates be high and Government / UNICEF recommend taking measures to mitigate against the risk of Covid-19 at the time of the research. The plan is split into 3 parts, such as protocols: (i) Before data collection and during training, (ii) During data collection, and (iii) After data collection.

Before data collection and during training

The following steps will be followed during the interviewers' training.

- Make sure everyone in the team (team leaders, and interviewers etc.) are up to date on the most recent information from the WHO and National Health Authority of our country and adhere to their guidelines.
- Check the temperature for the field personnel every morning**.** Inform the trainers in case anyone having a high temperature (above 37.5 Celsius), or any other mild symptoms such as tiredness, dry cough (common symptoms), shortness of breath, aches and pains, sore throat, or runny nose (other symptoms). Any person with these symptoms shall not be allowed to participate in the training and be sent home for self-quarantine for 14 days.
- Trainers to ask if any interviewers have been in contact with anyone being a confirmed or suspected case of COVID-19. If yes, the person should not continue participating in the training and be sent for self-quarantine for a minimum of 14 days.
- Wash hands thoroughly and regularly (ideally every 1 to 2 hours) with soap and water or alcohol-based hand rub.
- Follow the recommended cough etiquette at all times.
- Do not touch your (or anyone else's) face – particularly eyes, nose and mouth.
- Keep at least 1 metre distance from other people at all times**.** Don't have any physical contact with other people. That includes, no greetings such as handshakes, hugs, etc.
- Sanitize all data collection items prior to each interview (pens, phone, tablets, notebooks, ID cards, etc.)
- Don't spit in public and use mask always
- Ensure items are not shared among team members
- Provide pens for each individual staff member
- Provide zip-locked bags to place researcher phones/devices

During data collection

Each interviewer will receive a package with materials supplies for staff screening and sanitation (for individuals as well as of common and personal objects) before starting the field work, including thermometers, masks and hand hygiene items.

The following issues will be followed during the data collection in the field:

- Every morning remind the teams of the general guidance and protocols
- Approach respondent(s) for interviews/ discussions in line with the required measures

- Inform the respondent(s) of the COVID-19 measures (based on existing guidelines and messaging in the country) in a clear manner, prior to starting the interview or discussion
- Maintain the recommended distance (at least 1 metre) when approaching respondents
- Avoid physical contact (handshaking, hugging, etc.) to greet respondents. As this may be perceived as culturally inappropriate, clearly explain why you are doing this.

Conduct the interviews/discussions following the required measures:

- Conduct the interview/ discussion outside the house, if possible
- Maintain at least 1 metre distance from other people throughout, specifically the respondents.
- Avoid contact with elderly or people with chronic diseases, if possible
- Don't pass on things to other people, e.g. bottles, pens, phones, leaflets, visibility material etc. If you do so, wash your hands and wipe off the item carefully with disinfectant gel
- Don't drink or eat from the same containers and don't use utilities from another person.
- Wash hands with soap/sanitizer following advisories by WHO and/ or national authorities

After data collection

The following issues will be followed **after data collection** in the field:

- Ensure all staff returning from data collection thoroughly wash their hands with soap (at least 20 seconds)
- Ensure researchers are reporting back to field supervisor as established in the protocols
- Researchers should report to field supervisor for any health symptoms such as a high temperature (above 37.5), or any other mild symptoms such as tiredness, dry cough (common symptoms), shortness of breath, aches and pains, sore throat, or runny nose (other symptoms). If any staff is experiencing symptoms they should self-quarantine for at least 14 days/ until recovered.
- Researchers should confirm location and report of any interaction with an interviewee that exhibited symptoms of fever, cough or shortness of breath
- Researchers submit the data collected and clean data collection devices on a daily basis
- Researchers to upload their forms to the server on a daily basis (this needs to be covered in the training)
- Researchers to wipe off all devices with disinfectant or soap and water before handing them back and place all phones in a zip-locked plastic bag with their name written on it. This is to ensure that devices change hands as little as possible.

Should face to face data collection note be possible at all, researchers will consult with UNICEF to consider altenative methods of data collection (i.e. online interviews via Zoom / Phone / Whatsapp).

Criteria for Ethical Review Checklist

Does this evidence generation project/programme need to go through an ethical review process?

Does the project/programme Involve:	Yes	No
Children as participants, researchers and data collectors?	X	
Primary research specifically targeting persons with an illness, disability, mental health issue or persons in institutions?	X	
Primary research targetting and involving a group that may be perceived as vulnerable within the local context (e.g women, minority groups, persons with HIV/AIDS, the economically and educationally disadvantaged, persons in institutions, trafficked persons, persons who have or are experiencing violence?	X	
Primary research within humanitarian contexts (that is not routine monitoring/administrative data)?		
Primary research specifically exploring issues related to prevalence or experiences of, or attitudes towards, violence, abuse or trauma?		
Health-based assessments, diagnoses and treatments as part of the evidence generation programme?		
Data analysis of restricted access or non-anonymised data of individuals?		
Secondary data analysis where the findings may be sensitive?		
Merging of databases that will result in personal information becoming identifiable?		
The measurement and collection of health-related data, including assessments, diagnoses and the collection of biological samples?		
Primary data collection that involves questions on prevalence or experiences of, or attitudes towards, Violence, Abuse, Prostitution, Female Genital Mutilation, Political views, HIV/AIDS, Reproductive, sexual, reproductive and mental health?		
Primary data collection that involves questions that may be considered private or sensitive in the local context?		
Eliciting opinions for which fear may exist of public disclosure resulting in limitations to future freedoms and access to services?		
Randomised Control Trials involving the provision of cash transfers, or other goods and services, to one group and not to another group?		
The implementation of MICS within your country?		

If there is *at least* one tick in the 'yes' column (highlighted column) then the project/programme will need to go to review.

If there is no tick in the 'yes' column then this project/programme will merely be required to go through the traditional CO/RO quality assurance processes as determined by the relevant SOP.

An ethical Review may not be required when the evidence generation programme:

1. Uses only previously collected (secondary), de-identified data or samples (where there is no way to link the data or samples back to individuals)
2. Involves the collection of routine monitoring/administrative data
3. Undertakes a review of the literature (systematic reviews, literature reviews, rapid reviews) or involves analysis of information that is clearly publically available (websites, organisational reports) where the analysis and findings is unlikely to cause stigma to individuals and or their communities.
4. Where primary data collection is from experts or administrators and where publication of the findings and opinions will not cause harm to those participating.
5. Where primary data collection relates to;
    - non sensitive subjects and,
    - does not involve vulnerable groups and,
    - does not have the potential to compromise the confidentiality of data nor the privacy of individuals and,
    - does not threaten the safety or security of those involved or their communities and,
    - the risk of harm to participants and their community is limited or minimal
    - Does not involve unequal distribution of resources or access to services