Section in Guidelines	Original text	Comment by EUCROF
Section 2, para 7	Therefore, a code intended for transfers could frame transfers from controller/processors that do not adhere to that code of conduct to controller/processors in a third country having adhered to that code of conduct, provided that a commitment to comply with the obligations set forth by the code of conduct when processing the transferred data, including with regard to the rights of data subjects, is included in a binding instrument.	In the opinion of the working group providing the commnents to this Guidance, the utility of the *EUCROF Code of Conduct (EUCROF Code of Conduct) for the application of the GDPR to clinical research* (currently under review by the EU DPAs and if made as intended for transfer) may be decreased because the Guide disregards the common scenario in the domain of clinical research. In the current version, an importer outside of the EEA not adhering to the code and acting as a data controller cannot benefit from the code when receiving data from an exporter in the EEA that does adhere to the code and is acting as a data processor. Such scenario occurs in the clinical research when a pharmaceutical company (research sponsor and data controller) outside of the EEA engages a contract research organisation (CRO and data processor) in the EEA who arranges collection of data in the EEA and export of these data to the data controller outside of the EEA. The EUCROF Code of Conduct is intended for CROs/Processors. The sponsors/controllers are not able to adhere to this EUCROF Code. Therefore, the utility of the EUCROF Code is diminished if the importer has to be adhering to the Code in order to make the Code a valid transfer mechanism. It would mean that a very common scenario described above, would not benefit from a code of conduct intended for transfer. Our proposal is that the wording of the Guideline be amended to say that only one party to the transfer has to be adhering to the Code for the transfer to be effective under the Code, regardless of whether the adherent is the exporter or the importer. The justification for doing so is that under the Code, there must be a valid and binding data processing agreement between the parties in order to process personal data (which will have been approved by the supervisory authority), and that data processing agreement combined with the other measures of the Code should provide adequate safeguards in the same way that the standard contractual clauses do. There is precedent in the SCC module 4 to make the exporter (processor) ensure

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		that the importer (controller) will uphold the provisions of the SCC. Forethinking may be if the Guideline includes a scenario when the parties adhere to two different codes of conduct in the same domain, e.g., a CRO adheres to the EUCROF Code and a pharmaceutical company (sponsor and data controllers in clinical research) adheres to the sponsor's code of conduct in clinical research. In such scenario, parties should also be able to benefit from adherence to the codes that are developed to ensure compliance with the data protection laws.
Section 6.1, para 34, item 3	The existence of a right for the exporter to enforce against the code member the rules under the code as a third-party beneficiary.	To be clarified that this section refers to an exporter who is not a code member. If it is a code member, exporter should not be treated as a third-party beneficiary.
Section 6.1, para 34, item 4	The existence of an obligation to notify the exporter and the Supervisory Authority of the data exporter of any detected violation of the code by the code member outside the EEA and of any corrective measures taken by the monitoring body in response to that violation.	We are of the opinion that the meaning is ambiguous and seems to combine different points. We propose the sentence should be reworded to clarify: 1) whom the obligation refers to: the importer or monitoring body? We think it should refer to violation of the code by the importer of the data *that is the code adherent*. Such clarification should add clarity in cases there are multiple importers involved in a processing activity. 2) whether the report to the Supervisory Authority supplements or replaces or is the same as any report made under article 33 GDPR. 3) that the corrective actions in relation to the violation of the code should be made by the code adherent not the monitoring body. The monitoring body should oversee the implementation of the corrective action.

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Section 6.2, para 35	<…> the EDPB is of the view that to be considered as providing appropriate safeguards, the elements to be covered by a code of conduct intended for transfers should include the following: <…> A warranty that at the time of adhering to the code, the third country controller/processor has no reasons to believe that the laws applicable to the processing of personal data in the third country of transfer, prevent it from fulfilling its obligations under the code <...>.	We comment that the legal effect of a warranty is that it would create a right to damages for the innocent party and we think this is disproportionately unfair on the party giving the warranty. The expectation that a company (which may be a SME) should know whether there are laws of its country that would prevent it from fulfilling its obligations, is a onerous one and many companies would be unwilling/unable (e.g., discouraged by legal advisors) to give a warranty in this regard. In our opinion, essential is that the Guidlines clarify what legal test the adherents to a code should apply to declare/prove "no reasons to believe". Is that a reasonableness test, i.e. what would a reasonable person in that position know or ought to know? A clarification would be appreciated on an alternative to a warranty that a company could include as a safeguard. For example, such safeguard may be that the code adherent does a transfer impact assessment to evaluate and demonstrate whether, to their best judgement, there are laws applicable to the processing of personal data in the third country of transfer that prevent the code adherent from fulfilling its obligations under the code.

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Section 6.2, para 35	<…> the EDPB is of the view that to be considered as providing appropriate safeguards, the elements to be covered by a code of conduct intended for transfers should include the following: <…> supplementary measures to ensure the required level of protection under EEA law.	In our opinion, a code intended for transfer should provide code adherents with the recommendations on what constitutes supplementary safeguards specific to the code's domain/industry, e.g., clinical research. Therefore, we propose that the line "<...> supplementary measures to ensure the required level of protection under EEA law" be complemented with: "<...> the code shall define the minimal protective measures recognised as the basic technical and organisational safeguards required in the domain of the code of conduct, and supply examples of other appropriate measures specific for the code's domain. Any organization adhering to the code of conduct shall be required to implement these basic measures outlined by the code intended for transfer, as well as introduce any other measures as they appropriate in accordance with their assessment."
ANNEX 1	flow chart "a-The draft code is a “transnational code” and/or a code intended for transfer"	Should say "initial adoption process"
ANNEX 1	flow chart "b-The draft code is a “transnational code”"	Should say "amendment adoption process"