

Tool 1 — Neurodata Governance Decision Tool

Supplementary Table 6

Scientist-facing decision tool for assigning a provisional functional-exposure tier (5, 4, 3, 2, 1b, 1) to the particular neurodata object or artefact for the intended recipient, and for identifying the corresponding baseline safeguards. Highest tier governs; an Unknown answer takes the more protective branch; Step 0B may raise the minimum tier. Tier assignment supports governance decisions and does not establish legal classification or authorise processing.

Tier 1b: participant-level neurodata or derivative neurodata from which direct identifiers, identifying anatomy and identifying acquisition metadata have been removed, for which no code, key or institutional mapping is available to the intended recipient, and for which a documented disclosure-risk assessment concludes that no individual or small group can reasonably be identified by means reasonably likely to be used by that recipient (for public release: by any member of the public). Minimum measures: documented de-identification method; written confirmation of the absence of a linkage mechanism; Step 8 disclosure-risk assessment; licence or access condition prohibiting re-identification; record that legal status is recipient-relative.

Step	Question	Answer	Risk tier	Required action
Applicability checkpoint	Which statutory access regimes and ex ante data-protection, privacy-impact or privacy-risk assessment requirements may apply to the proposed activity? Consider the data category, holder, purpose, jurisdiction and application date, including EHDS where relevant. Assess legal applicability separately from functional-exposure tier.	Complete checkpoint	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record potentially applicable regimes and assessment requirements in Neurodata Governance Assessment Record (Schedule B of the MDTAA) Record any unresolved applicability question and refer it to the responsible legal or institutional reviewer in Neurodata Governance Assessment Record (Schedule B of the MDTAA) Continue to Step 1. Completion of this checkpoint does not resolve or waive an outstanding legal requirement.
0B	Participant status. Do the neurodata relate, in whole or in part, to (a) minors; (b) adults who lacked capacity to consent at collection; (c) deceased persons; (d) members of an Indigenous people or a community-governed or otherwise defined population with recognised governance interests; or (e) persons in a dependent relationship with the collecting institution (patients, employees, students, detainees)?	Yes (select all that apply)	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record each applicable status and the consent, assent, proxy-consent, community-approval or post-mortem rule relied on under Applicable Law in the Neurodata Governance Assessment Record (Schedule B of the MDTAA). Treat the minimum tier available at the Final Decision as one tier higher than otherwise determined (Tier 1 → Tier 1b; Tier 1b → Tier 2), unless a documented ethics or community determination permits otherwise. Where (d) applies, mark Tool 4 (Supplementary Table 9) Step 17 as required. Continue to Step 1.

Step	Question	Answer	Risk tier	Required action
0B	Participant status. Do the neurodata relate, in whole or in part, to (a) minors; (b) adults who lacked capacity to consent at collection; (c) deceased persons; (d) members of an Indigenous people or a community-governed or otherwise defined population with recognised governance interests; or (e) persons in a dependent relationship with the collecting institution (patients, employees, students, detainees)?	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the basis for the answer in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 1.
0B	Participant status. Do the neurodata relate, in whole or in part, to (a) minors; (b) adults who lacked capacity to consent at collection; (c) deceased persons; (d) members of an Indigenous people or a community-governed or otherwise defined population with recognised governance interests; or (e) persons in a dependent relationship with the collecting institution (patients, employees, students, detainees)?	Unknown	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the uncertainty; obtain the information from the Principal Investigator or data steward. Apply the 'Yes' action provisionally. Continue to Step 1.
1	Does this object contain, represent or derive from human neurodata? ? Examples include MRI, fMRI, EEG, MEG, ECoG, neural implant data, BCI recordings, neural features, embeddings, predictions, or AI models trained using neurodata.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record why the object falls outside this Tool's scope in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Record the outcome as "Not applicable" in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Follow the institution's ordinary data-governance procedures. End this Tool.

Step	Question	Answer	Risk tier	Required action
1	Does this object contain, represent or derive from human neurodata? ? Examples include MRI, fMRI, EEG, MEG, ECoG, neural implant data, BCI recordings, neural features, embeddings, predictions, or AI models trained using neurodata.	Yes	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the object's human-neurodata source or relationship in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 2A.
1	Does this object contain, represent or derive from human neurodata? ? Examples include MRI, fMRI, EEG, MEG, ECoG, neural implant data, BCI recordings, neural features, embeddings, predictions, or AI models trained using neurodata.	Unsure	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the uncertainty in Neurodata Governance Assessment Record (Schedule B of the MDTAA) Obtain clarification from the Principal Investigator, data steward or technical lead before beginning the proposed sharing or analysis. Pause this assessment. Return to Step 1 when the evidence supports "Yes" or "No".
2A	Is the object under assessment itself a trained AI model, model component, model gradient, shared embedding store, synthetic-data generator, federated-learning artefact or other persistent computational artefact that was trained on, fitted to or otherwise derived from human neurodata? Examples include model weights, foundation models, federated-learning systems, synthetic-data generators, model gradients, or shared embedding repositories.	Yes	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the artefact, its version and the form of incorporation in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Mark Tool 3 (Supplementary Table 8) as required for this object. Continue to Step 2B.

Step	Question	Answer	Risk tier	Required action
2A	Is the object under assessment itself a trained AI model, model component, model gradient, shared embedding store, synthetic-data generator, federated-learning artefact or other persistent computational artefact that was trained on, fitted to or otherwise derived from human neurodata? Examples include model weights, foundation models, federated-learning systems, synthetic-data generators, model gradients, or shared embedding repositories.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the basis for this answer in Neurodata Governance Assessment Record (Schedule B of the MDTAA). If a model has been or will be trained on this object, note that the model is a separate object requiring its own Tool 1 and Tool 3 assessment. Continue to Step 3.
2A	Is the object under assessment itself a trained AI model, model component, model gradient, shared embedding store, synthetic-data generator, federated-learning artefact or other persistent computational artefact that was trained on, fitted to or otherwise derived from human neurodata? Examples include model weights, foundation models, federated-learning systems, synthetic-data generators, model gradients, or shared embedding repositories.	Unknown	Tier 5	Record provisional Tier 5 in Neurodata Governance Assessment Record (Schedule B of the MDTAA) and apply the Tier 5 safeguards specified in Annexure 1 §3.5 to the relevant object and activity. Request technical confirmation of whether incorporation has occurred. Continue to Step 3 to identify additional exposure and safeguards. When clarification is available, return to Step 2A: if "Yes", continue to Step 2B; if "No", document resolution of this provisional finding and continue to Step 3. Do not finalise a lower tier or proceed with affected sharing, transfer or deployment while this uncertainty remains unresolved.
2B	Is there evidence, or a reasonable possibility, that neural information persists within the model or computational infrastructure in a manner capable of supporting identification, inference, reconstruction, extraction or profiling of individuals or groups? Consider model memorisation, inversion, membership inference, extraction attacks, reconstructive outputs, shared embeddings and other forms of persistent representation.	Yes	Tier 5	Record a provisional Tier 5 condition in Neurodata Governance Assessment Record (Schedule B of the MDTAA) and apply Tier 5 safeguards provisionally under Annexure 1 §3.5. Record the evidence or credible technical assessment supporting continuing functional exposure in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Initiate or complete Tool 3 (Supplementary Table 8) and apply the Tool 3 (Supplementary Table 8) return procedure below. Continue to Step 3 to identify additional exposure and safeguards. Tier 5 remains unconfirmed until the required assessment establishes its criteria
2B	Is there evidence, or a reasonable possibility, that neural information persists within the model or computational infrastructure in a manner capable of supporting identification, inference, reconstruction, extraction or profiling of individuals or groups? Consider model memorisation, inversion, membership inference, extraction attacks, reconstructive outputs, shared embeddings and other forms of persistent representation.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the supporting technical assessment in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Complete Tool 3 (Supplementary Table 8) because Step 2A was answered "Yes"; this answer does not remove that requirement. Apply the Tool 3 (Supplementary Table 8) return procedure below. Continue to Step 3. Do not remove an existing higher-tier finding solely on the basis of this answer.

Step	Question	Answer	Risk tier	Required action
2B	Is there evidence, or a reasonable possibility, that neural information persists within the model or computational infrastructure in a manner capable of supporting identification, inference, reconstruction, extraction or profiling of individuals or groups? Consider model memorisation, inversion, membership inference, extraction attacks, reconstructive outputs, shared embeddings and other forms of persistent representation.	Unknown	Tier 5	Record provisional Tier 5 in Neurodata Governance Assessment Record (Schedule B of the MDTAA) and apply Tier 5 safeguards under Annexure 1 §3.5. Record the unresolved exposure question in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Obtain appropriate specialist technical, legal, ethics or institutional review and complete Tool 3 (Supplementary Table 8). Apply the Tool 3 (Supplementary Table 8) return procedure below. Continue to Step 3 to identify additional exposure and safeguards. Do not finalise a lower tier or proceed with affected sharing, transfer or deployment until the uncertainty is resolved.
3	Is this object a derived neurodata product rather than the original neurodata? ? Examples include embeddings, feature vectors, neural fingerprints, cognitive profiles, classifiers, predictions, or reconstructed neural representations.	Yes	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the source neurodata and the transformation that produced the object in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 4.
3	Is this object a derived neurodata product rather than the original neurodata? ? Examples include embeddings, feature vectors, neural fingerprints, cognitive profiles, classifiers, predictions, or reconstructed neural representations.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the basis for treating the object as original neurodata. in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 5 to assess direct identification and traceability.
3	Is this object a derived neurodata product rather than the original neurodata? ? Examples include embeddings, feature vectors, neural fingerprints, cognitive profiles, classifiers, predictions, or reconstructed neural representations.	Unknown	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Obtain provenance or processing information from the data steward or technical lead. Retain all existing tier findings and safeguards. Pause progression beyond this step. Return to Step 3 when the evidence supports "Yes" or "No".

Step	Question	Answer	Risk tier	Required action
4	Does this derived object have excess inferential capacity, that is, can it, alone or with information reasonably available to the intended recipient: (i) support inference about neurological, cognitive, emotional or behavioural states or traits outside the purpose for which the source neurodata were authorised; (ii) identify or trace a participant by itself (for example a functional-connectome fingerprint or a high-dimensional embedding unique to a participant); or (iii) reconstruct stimuli, speech, imagery or neural signals? Standard summary derivatives that reveal no more than the source dataset already reveals (for example regional volumes, connectivity matrices or spectral summaries used for the authorised purpose) do not satisfy this question and retain the source tier. Apply Annexure 1 §4.1.6 and the §2.1 distinction between ordinary aggregate description and material group-level Functional Exposure.	Yes	Tier 4	Record a Tier 4 finding and the relevant capability in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Restrict access to controlled access; document permitted uses and prohibited inferences in Neurodata Governance Assessment Record (Schedule B of the MDTAA); prohibit unauthorised profiling, reconstruction and general-purpose AI training; and maintain provenance records. Obtain specialist governance review and complete Tool 3 (Supplementary Table 8). Complete Neuro-TADT (Tool 2) (Supplementary Table 7) before external sharing or international transfer. Retain any higher tier finding. Continue to Step 5.
4	Does this derived object have excess inferential capacity, that is, can it, alone or with information reasonably available to the intended recipient: (i) support inference about neurological, cognitive, emotional or behavioural states or traits outside the purpose for which the source neurodata were authorised; (ii) identify or trace a participant by itself (for example a functional-connectome fingerprint or a high-dimensional embedding unique to a participant); or (iii) reconstruct stimuli, speech, imagery or neural signals? Standard summary derivatives that reveal no more than the source dataset already reveals (for example regional volumes, connectivity matrices or spectral summaries used for the authorised purpose) do not satisfy this question and retain the source tier. Apply Annexure 1 §4.1.6 and the §2.1 distinction between ordinary aggregate description and material group-level Functional Exposure.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the evidence supporting this answer in Neurodata Governance Assessment Record (Schedule B of the MDTAA), including why the derivative reveals no more than the source dataset and the additional information reasonably available to the intended recipient. Continue to Step 5.

Step	Question	Answer	Risk tier	Required action
4	Does this derived object have excess inferential capacity, that is, can it, alone or with information reasonably available to the intended recipient: (i) support inference about neurological, cognitive, emotional or behavioural states or traits outside the purpose for which the source neurodata were authorised; (ii) identify or trace a participant by itself (for example a functional-connectome fingerprint or a high-dimensional embedding unique to a participant); or (iii) reconstruct stimuli, speech, imagery or neural signals? Standard summary derivatives that reveal no more than the source dataset already reveals (for example regional volumes, connectivity matrices or spectral summaries used for the authorised purpose) do not satisfy this question and retain the source tier. Apply Annexure 1 §4.1.6 and the §2.1 distinction between ordinary aggregate description and material group-level Functional Exposure.	Unknown	Tier 4	Record provisional Tier 4 and the capability requiring assessment in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Apply the safeguards specified in the Step 4 "Yes" row provisionally. Complete Tool 3 (Supplementary Table 8) and obtain the specialist review needed to resolve the uncertainty. Retain any higher tier finding. Continue to Step 5.
5	Does the object contain direct identifiers, recognisable identifying anatomy, identifying acquisition metadata, or intrinsic information that reasonably permits participant identification or tracing beyond linkage through a separately protected code or mapping? Examples include names, identifying DICOM headers, non-defaced facial anatomy, identifying voice or video, or device identifiers and timestamps that enable tracing. Being a raw EEG, MEG, ECoG or MRI acquisition is not, by itself, a "Yes"; linkage solely through a protected code or mapping is assessed at Step 6.	Yes	Tier 3	Record a Tier 3 finding and the identifiers or intrinsic traceability identified in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Store the object in a secure controlled environment with encryption, role-based access, audit logs, and formal access approval. Remove unnecessary identifiers where feasible and restrict downloads and onward sharing. Complete Neuro-TADT (Tool 2) (Supplementary Table 7) before international transfer or external access. Retain any higher tier finding. Continue to Step 6.
5	Does the object contain direct identifiers, recognisable identifying anatomy, identifying acquisition metadata, or intrinsic information that reasonably permits participant identification or tracing beyond linkage through a separately protected code or mapping? Examples include names, identifying DICOM headers, non-defaced facial anatomy, identifying voice or video, or device identifiers and timestamps that enable tracing. Being a raw EEG, MEG, ECoG or MRI acquisition is not, by itself, a "Yes"; linkage solely through a protected code or mapping is assessed at Step 6.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the basis for concluding that the specified identifiers and intrinsic traceability are absent in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 6.

Step	Question	Answer	Risk tier	Required action
5	Does the object contain direct identifiers, recognisable identifying anatomy, identifying acquisition metadata, or intrinsic information that reasonably permits participant identification or tracing beyond linkage through a separately protected code or mapping? Examples include names, identifying DICOM headers, non-defaced facial anatomy, identifying voice or video, or device identifiers and timestamps that enable tracing. Being a raw EEG, MEG, ECoG or MRI acquisition is not, by itself, a “Yes”; linkage solely through a protected code or mapping is assessed at Step 6.	Unknown	Tier 3	Record provisional Tier 3 in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Apply the safeguards specified in the Step 5 “Yes” row provisionally. Assign an identifier and traceability review to the responsible data steward or technical reviewer. Retain any higher tier finding. Continue to Step 6. Return to Step 5 when the review supports “Yes” or “No”.
6	Does the object still contain participant-level neurodata that can be linked back to an individual through a code, repository record or institutional key that is available to, or obtainable by, the intended recipient? Where a key exists but is held by another party under a documented undertaking not to disclose it, answer ‘No’ for that recipient and ‘Yes’ for the key-holder, and record both. Example: a pseudonymised EEG dataset whose participant identifiers are held by the originating institution (‘Yes’ for the originating institution; ‘No’ for an external recipient that has no access to the key).	Yes	Tier 2	Record a Tier 2 finding, the linkage mechanism and the responsible custodian in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Use controlled-access repositories; separate and protect the linkage key; encrypt data in storage and transit; maintain access logs; and restrict re-identification and onward sharing. Put any required Data Use or Transfer Agreement in place before the relevant access or transfer. Where another institution holds the key, record its custody and restrictions without obtaining or disclosing the key. Retain any higher tier finding. Proceed to the Final Decision.
6	Does the object still contain participant-level neurodata that can be linked back to an individual through a code, repository record or institutional key that is available to, or obtainable by, the intended recipient? Where a key exists but is held by another party under a documented undertaking not to disclose it, answer ‘No’ for that recipient and ‘Yes’ for the key-holder, and record both. Example: a pseudonymised EEG dataset whose participant identifiers are held by the originating institution (‘Yes’ for the originating institution; ‘No’ for an external recipient that has no access to the key).	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the evidence that no linkage mechanism is available to the intended recipient (key destroyed; or key-holder identified with its undertaking recorded) in Neurodata Governance Assessment Record (Schedule B of the MDTAA). If a candidate, provisional or confirmed Tier 3, Tier 4 or Tier 5 finding remains active, proceed to the Final Decision. Otherwise, continue to Step 7.
6	Does the object still contain participant-level neurodata that can be linked back to an individual through a code, repository record or institutional key that is available to, or obtainable by, the intended recipient? Where a key exists but is held by another party under a documented undertaking not to disclose it, answer ‘No’ for that recipient and ‘Yes’ for the key-holder, and record both. Example: a pseudonymised EEG dataset whose participant identifiers are held by the originating institution (‘Yes’ for the originating institution; ‘No’ for an external recipient that has no access to the key).	Unknown	Tier 2	Record provisional Tier 2 in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Apply the linkage safeguards specified in the Step 6 “Yes” row to any existing or potentially retained linkage mechanism. Request confirmation from the data holder or repository custodian about whether participant-level linkage remains possible. Retain any higher tier finding. Proceed to the Final Decision with the uncertainty unresolved. When confirmation is available, return to Step 6 and follow the “Yes” or “No” branch.

Step	Question	Answer	Risk tier	Required action
7	Does the object contain only aggregated or summary-level information with no participant-level records or persistent participant trace? Example: A published study reporting only group-average brain activation patterns, summary statistics, or aggregate connectivity measures with no participant-level records or re-identifiable individual data.	Yes	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record the aggregation or summarisation method and the evidence that no participant-level records or persistent participant trace remain in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 8.
7	Does the object contain only aggregated or summary-level information with no participant-level records or persistent participant trace? Example: A published study reporting only group-average brain activation patterns, summary statistics, or aggregate connectivity measures with no participant-level records or re-identifiable individual data.	No	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record that the object contains participant-level records without an available linkage mechanism (candidate Tier 1b) in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Continue to Step 8 for the disclosure-risk assessment. Do not record 'Unclassified' at this step.
7	Does the object contain only aggregated or summary-level information with no participant-level records or persistent participant trace? Example: A published study reporting only group-average brain activation patterns, summary statistics, or aggregate connectivity measures with no participant-level records or re-identifiable individual data.	Unknown	No tier is assigned at this step. Follow the instructions in the Required action column. Any tier identified at an earlier step remains applicable unless resolved through documented reassessment.	Record that aggregate-only status has not been established Neurodata Governance Assessment Record (Schedule B of the MDTAA). Request technical review of participant-level records, persistent traces and the aggregation or summarisation method. Pause classification and retain any existing safeguards. Do not approve release through this Tool while the uncertainty remains unresolved. Return to Step 7 when the evidence supports "Yes" or "No".

Step	Question	Answer	Risk tier	Required action
8	Could an individual or small group still reasonably be identified by means reasonably likely to be used by the intended recipient (for public release: by any member of the public), through rare conditions, small sample sizes, unique characteristics, intrinsic signal characteristics known to permit re-identification for this modality (for example residual facial features after defacing; connectome fingerprints), accompanying metadata, or linkage with data reasonably available to the recipient? Example: a dataset describing a single participant with a rare neurological disorder, a very small cohort from one clinic, or records containing unique demographic or geographic metadata.	Yes	Tier 2 (minimum)	Record Tier 2 as the minimum applicable tier and identify the disclosure mechanism in Neurodata Governance Assessment Record (Schedule B of the MDATA). Increase aggregation, suppress disclosive information or strengthen de-identification where feasible. Determine and record the necessary access restrictions, including controlled access where required. Reassess the modified object before release, repeating Steps 5–8 and any earlier step affected by the modification. Retain any higher tier finding unless documented reassessment resolves it. Proceed to the Final Decision.
8	Could an individual or small group still reasonably be identified by means reasonably likely to be used by the intended recipient (for public release: by any member of the public), through rare conditions, small sample sizes, unique characteristics, intrinsic signal characteristics known to permit re-identification for this modality (for example residual facial features after defacing; connectome fingerprints), accompanying metadata, or linkage with data reasonably available to the recipient? Example: a dataset describing a single participant with a rare neurological disorder, a very small cohort from one clinic, or records containing unique demographic or geographic metadata.	No — and the object is aggregate-only (Step 7 'Yes')	Tier 1 Note: A Tier 1 outcome does not automatically exclude Annexure 3 in the MDATA. Apply the exception and triggers in Annexure 1 §7.2 in the MDATA to the particular object and proposed activity, and record the reason for completing or omitting Annexure 3 in the MDATA. A Tier 1 outcome shall not override a higher candidate, provisional or confirmed tier identified elsewhere in the assessment.	Record a Tier 1 finding and the supporting disclosure-risk assessment in Neurodata Governance Assessment Record (Schedule B of the MDATA). Document the aggregation or anonymisation method and confirm that no participant-level record, persistent participant trace or linkage mechanism remains in Neurodata Governance Assessment Record (Schedule B of the MDATA). Check the triggers and exceptions in Annexure 1 §7.2 and record why Tool 3 (Supplementary Table 8) is required or may be omitted. Do not use this finding to override a higher candidate, provisional or confirmed tier. Proceed to the Final Decision.

Step	Question	Answer	Risk tier	Required action
8	Could an individual or small group still reasonably be identified by means reasonably likely to be used by the intended recipient (for public release: by any member of the public), through rare conditions, small sample sizes, unique characteristics, intrinsic signal characteristics known to permit re-identification for this modality (for example residual facial features after defacing; connectome fingerprints), accompanying metadata, or linkage with data reasonably available to the recipient? Example: a dataset describing a single participant with a rare neurological disorder, a very small cohort from one clinic, or records containing unique demographic or geographic metadata.	No — and the object is participant-level (Step 7 'No')	Tier 1b Note: a Tier 1b finding is made for a specified recipient (or for the public) and may differ from the tier applying to the Data Exporter, which may retain a key (Tier 2). A Tier 1b outcome shall not override a higher candidate, provisional or confirmed tier identified elsewhere in the assessment.	Record a Tier 1b finding and the supporting disclosure-risk assessment in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Document the de-identification method (including defacing, header stripping and date shifting, with software and version), the absence of an available linkage mechanism, and the recipient (or 'public') for which the finding is made. Select and record the licence or access condition required by Annexure 1 §3.1b(d), including a prohibition on re-identification attempts. Apply any uplift required by Step 0B. Check the triggers and exceptions in Annexure 1 §7.2 and record why Tool 3 (Supplementary Table 8) is required or may be omitted. Do not use this finding to override a higher candidate, provisional or confirmed tier. Proceed to the Final Decision.
8	Could an individual or small group still reasonably be identified by means reasonably likely to be used by the intended recipient (for public release: by any member of the public), through rare conditions, small sample sizes, unique characteristics, intrinsic signal characteristics known to permit re-identification for this modality (for example residual facial features after defacing; connectome fingerprints), accompanying metadata, or linkage with data reasonably available to the recipient? Example: a dataset describing a single participant with a rare neurological disorder, a very small cohort from one clinic, or records containing unique demographic or geographic metadata.	Unknown	Tier 2	Record provisional Tier 2 in Neurodata Governance Assessment Record (Schedule B of the MDTAA). Obtain a disclosure-risk review addressing rare conditions, small samples, unique characteristics, and accompanying metadata. Withhold release pending resolution of this uncertainty. Retain any higher tier finding. Proceed to the Final Decision with the uncertainty unresolved. Return to Step 8 when the review supports "Yes" or "No".
Final Decision	Have all applicable steps and required classification reviews been completed?	Complete assessment	-	Record the highest applicable tier and whether it is provisional or confirmed. Do not finalise a lower tier while a higher candidate or provisional finding remains unresolved. Retain all safeguards whose underlying conditions remain present. Save the outcome, supporting evidence, outstanding actions and responsible reviewer in the assessment record; incorporate or reference it in Neurodata Governance Assessment Record (Schedule B of the MDTAA). where applicable. Complete or update Tools 2 (Supplementary Table 7) and 3 (Supplementary Table 8) where required, then proceed to Tool 4 (Supplementary Table 9) where contractual implementation is needed. Do not begin the proposed activity until required safeguards and approvals are in place. Apply any tier uplift recorded at Step 0B before finalising.

Tool 2 — Neurodata Transfer and Access Decision Tool (Neuro-TADT)

Supplementary Table 7

Assesses whether the safeguards associated with the assigned tier can be implemented and maintained across a proposed sharing, repository, remote-access, cloud, federated or cross-border pathway, including the gated public-release branch (Step 3), the compatibility-class lookup (Step 6A), origin- and destination-side restrictions (Step 6B) and exporter/importer checks (Step 7). Produces four outcomes. Completion does not determine that a transfer is lawful.

Step	Question	Answer	Required action
<i>General instructions before using this tool: Assess the proposed transfer or access arrangement using the tier and safeguards identified in Supplementary Table 6. Wherever this Tool says "record", enter the information against the relevant step in the transfer and access section of the Neurodata Governance Assessment Record. Where the MDTAA applies, incorporate or reference that assessment in Schedule C and link it to the classification recorded in Schedule B. Record supporting evidence, outstanding actions and responsible persons. Continuing through the assessment does not authorise transfer or access. A later answer does not remove an earlier restriction or unresolved requirement. Before Step 7, complete the pathway lookup at Step 6A and the restrictions check at Step 6B; the actions recorded there are prerequisites for Outcome 1 or 2.</i>			
1	What are you planning to do with the neurodata? Example: Using an EEG dataset to train a machine learning model for early detection of Alzheimer's disease.	Internal use only with no external or cross border sharing or access to data.	Record the internal use and why no listed external or cross-border pathway applies. Apply the safeguards identified in Supplementary Table 6 and assess applicable statutory access and authorisation requirements. Record "Neuro-TADT not required for this arrangement" and end this Tool. Other applicable governance assessments remain required
1	What are you planning to do with the neurodata? Example: Using an EEG dataset to train a machine learning model for early detection of Alzheimer's disease.	Share with another institution; international transfer; repository deposit; cloud-hosted access; or AI platform or vendor access.	Record every selected pathway and the proposed activity. Continue to Step 2.
1	What are you planning to do with the neurodata? Example: Using an EEG dataset to train a machine learning model for early detection of Alzheimer's disease.	Unsure	Obtain clarification of the proposed storage, sharing, access and processing arrangements. Pause the assessment and do not begin the proposed transfer or external access. Return to Step 1 when the pathway is established.
2	Has the neurodata already been assigned a risk tier using (Tool 1) Supplementary Table 6? Example: The neurodata has been classified as Tier 2 (Moderate Risk) using the criteria in Supplementary Table 26 before planning further processing or sharing.	Yes	Record the tier, whether it is provisional or confirmed, the applicable safeguards and the (Tool 1) Supplementary Table 6 assessment reference. Carry forward all unresolved conditions and restrictions. A provisional tier may support pathway assessment but does not remove required review. Continue to Step 3.
2	Has the neurodata already been assigned a risk tier using (Tool 1) Supplementary Table 6? Example: The neurodata has been classified as Tier 2 (Moderate Risk) using the criteria in Supplementary Table 26 before planning further processing or sharing.	No	Complete (Tool 1) Supplementary Table 6 to get a risk tier assigned to the particular data object and proposed activity. Return to Step 2 after a tier has been assigned. If (Tool 1) Supplementary Table 6 cannot establish a tier and requires specialist review, select Final Decision Outcome 4 below.
2	Has the neurodata already been assigned a risk tier using (Tool 1) Supplementary Table 6? Example: The neurodata has been classified as Tier 2 (Moderate Risk) using the criteria in Supplementary Table 26 before planning further processing or sharing.	Unsure	Locate the existing classification and check that it covers the object, version and proposed activity. Complete or update records according to Supplementary Table 6 if the classification is absent or no longer applicable. Return to Step 2 when the tier and safeguards are established.

Step	Question	Answer	Required action
3	Who will receive or access the neurodata? Example: An approved research collaborator, an international research consortium, or a trusted cloud service provider processing the neurodata under a data processing agreement.	Named collaborating institution; repository; cloud provider; commercial partner; or AI developer. Select all that apply.	Record each recipient's name, role and proposed access or processing activity. Continue to Step 4.
3	Who will receive or access the neurodata? Example: An approved research collaborator, an international research consortium, or a trusted cloud service provider processing the neurodata under a data processing agreement.	Unknown recipients	Record which recipients remain unidentified. Obtain recipient information from the proposed collaborator, repository, provider or other responsible party. Do not begin transfer or access. Return to Step 3 once recipients are identified. If they cannot be identified, select Final Decision Outcome 4 below.
3	Who will receive or access the neurodata? Example: An approved research collaborator, an international research consortium, or a trusted cloud service provider processing the neurodata under a data processing agreement.	Public or unrestricted release (open repository deposit, open licence, public model weights, publication of participant-level supplementary data)	Record the release channel, licence and any registration or click-through conditions. Public release is permitted through this Tool only where (a) Tool 1 (Supplementary Table 6) records a confirmed Tier 1 or Tier 1b finding made for the public as recipient, or (b) for a model or other computational artefact, Tool 3 (Supplementary Table 8) Step 7 records leakage testing with no material exposure for the intended release conditions and a documented anonymity assessment. If neither condition is met, record 'Public release not supported by current classification' and either select Final Decision Outcome 3 (redesign: controlled access, gated or registered access, or federated access) or return the object to Tool 1/Tool 3 for further de-identification or testing. If a condition is met, record 'Recipients: public' at Steps 4 and 12, treat Step 5 as 'Downloadable copy', and continue to Step 6.
4	Can every recipient and subprocessor be identified? Example: All recipients are known by name, including collaborating institutions, cloud service providers, and any contracted subprocessors.	Yes	Record each recipient and subprocessor, its role and the information available about its access. Continue to Step 5.
4	Can every recipient and subprocessor be identified? Example: All recipients are known by name, including collaborating institutions, cloud service providers, and any contracted subprocessors.	No or Unsure	Request a complete recipient and subprocessor list from the responsible organisation or provider. Do not begin transfer or access while required identities remain unresolved. Return to Step 4 when the list is complete. If the required information cannot be established, select Final Decision Outcome 4 below.
4	Can every recipient and subprocessor be identified? Example: All recipients are known by name, including collaborating institutions, cloud service providers, and any contracted subprocessors.	Not applicable — public release recorded at Step 3	Record 'Not applicable: public release permitted under Step 3'. Continue to Step 5.
5	How will recipients access the neurodata or governed artefact? Example: The recipient can download and retain a local copy of the neurodata rather than accessing it only through a secure remote environment.	Downloadable copy	Record what may be downloaded, by whom and to which environment. Specify tier-appropriate controls for local storage, copying, access, onward sharing, retention and deletion. Continue to Step 6.
5	How will recipients access the neurodata or governed artefact? Example: The recipient can download and retain a local copy of the neurodata rather than accessing it only through a secure remote environment.	Remote or controlled access without downloading the underlying object	Record the access environment, authorised users and restrictions on downloading or exporting data and outputs. Specify access controls, logging and output review appropriate to the tier. Continue to Step 6.

Step	Question	Answer	Required action
5	How will recipients access the neurodata or governed artefact? Example: The recipient can download and retain a local copy of the neurodata rather than accessing it only through a secure remote environment.	Query-only or federated access	Record where processing occurs and what queries, outputs, gradients or other information may leave each environment. Specify controls on queries, outputs, access and logging appropriate to the tier. Continue to Step 6.
		Unsure	Obtain confirmation of the access modes and export capabilities from the recipient or infrastructure provider. Pause the assessment and do not begin access. Return to Step 5 when the access arrangements are established.
6	Will the neurodata be transferred to, stored in, or remotely accessed from another legal jurisdiction? Example: neurodata remains on a server in South Africa but is accessed remotely by researchers in Germany.	Yes	Record every relevant originating, receiving, hosting and remotely accessing jurisdiction, including relevant subprocessor locations. Continue to Step 7.
6	Will the neurodata be transferred to, stored in, or remotely accessed from another legal jurisdiction? Example: neurodata remains on a server in South Africa but is accessed remotely by researchers in Germany.	No	Record the locations and the basis for concluding that no cross-jurisdictional transfer, storage or remote access is involved. Continue to Step 7.
6	Will the neurodata be transferred to, stored in, or remotely accessed from another legal jurisdiction? Example: neurodata remains on a server in South Africa but is accessed remotely by researchers in Germany.	Unsure	Obtain location and remote-access information from the recipients and infrastructure providers. Do not begin transfer or access while relevant jurisdictions remain unresolved. Return to Step 6 when the locations are established. If they cannot be established, select Final Decision Outcome 4 below.
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	A1 (unified legal space)	Record 'A1: no transfer mechanism required'. The lawful basis for processing in both environments and any sector-specific or institutional condition remain required at Step 7. Continue to Step 6B.
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	A2 (convergent; adequacy-type recognition)	Record the adequacy decision, regulation or recognition relied on, its date and any scope limits (for example sectoral or organisational limits, as for Canada (commercial organisations) or the United States (DPF-certified organisations only)). Verify that the recipient falls within the scope; if it does not, treat the pathway as Class B. Continue to Step 6B.

Step	Question	Answer	Required action
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	B (standard transfer instrument)	Record the instrument required by the origin regime (see the Step 6B regime table and the MDTAA Transfer-Instrument Modules). Mark the corresponding MDTAA module for activation at Tool 4 (Supplementary Table 9) Step 2. Continue to Step 6B.
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	C (operationally conditional)	As for Class B, and in addition: mark Tool 4 Step 3 (Supplementary Safeguards Module) as required; require a documented transfer-risk or impact assessment at Step 7(i); and record the supplementary institutional, repository or technical safeguards that make the pathway navigable. Continue to Step 6B.
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	D (restricted in practice)	Record that the pathway is restricted. Default to Final Decision Outcome 3: redesign toward remote access, federated or query-only access, aggregation to Tier 1, or an alternative destination. Proceed with a transfer of participant-level data only where counsel in the origin jurisdiction documents a lawful mechanism and the authorisations required at Step 6B. Continue to Step 6B.
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	E (insufficient legal certainty)	Record that legal certainty is insufficient. Default to Final Decision Outcome 4 unless counsel in the origin jurisdiction documents a lawful mechanism; where that is done, treat the pathway as Class D. Continue to Step 6B.

Step	Question	Answer	Required action
6A	Pathway class. What is the compatibility class of the origin→destination pathway (and of each origin→hosting and origin→remote-access pathway) in Supplementary Data 2 (or the current online version of the matrix)? Record the matrix version and date. Where the destination is the United States or Canada, use the North American governance-unit analysis (Supplementary Figure 1) and record the applicable federal, state or provincial regime instead of a class. Example: Nigeria → Germany is Class B; Germany → Brazil was Class C at the study cut-off and is adequacy-based (Class A2) since 26 January 2026.	Not in matrix / Unsure	Record the gap. Obtain an origin-jurisdiction legal assessment and treat the pathway as Class C pending that assessment. Continue to Step 6B.
6B	Origin-side and destination-side restrictions. Using the Step 6B regime table (and Supplementary Data 3 for jurisdictions not listed), does any of the following apply? (a) a statutory prohibition on transferring this category of data or this type of database (e.g., LGPD art. 13 §2); (b) a localisation, serving-copy or in-country processing duty (e.g., Kenya reg. 26; Rwanda art. 50); (c) a requirement of prior authorisation, notification, licence or registration by a regulator before transfer or storage abroad (e.g., POPIA s. 57(1)(d); NCSA authorisation); (d) sanctions, export-control or national-security screening of the destination or recipient (e.g., US DOJ Data Security Program, 28 CFR Part 202; OFAC) where any Party is a US person or the data concern US persons; (e) a research export permit, ethics-committee export clearance or data-transfer approval required by the origin jurisdiction (e.g., NACOSTI; NHREC); (f) a destination-side import condition (registration, local representative, sectoral hosting certification such as HDS in France).	Yes (select all that apply)	Record each applicable restriction, the responsible Party, the competent authority and the evidence required. Where (a) applies, select Final Decision Outcome 3 (redesign so that no transfer of the prohibited category occurs, for example analysis within the origin environment with export of results only) or Outcome 4. Where (b)–(f) apply, mark each as a prerequisite: Outcome 1 may not be selected until the authorisation, registration, serving copy, screening or permit is documented; Outcome 2 may be selected where the action is pending. Continue to Step 7(i).
6B	Origin-side and destination-side restrictions. Using the Step 6B regime table (and Supplementary Data 3 for jurisdictions not listed), does any of the following apply? (a) a statutory prohibition on transferring this category of data or this type of database (e.g., LGPD art. 13 §2); (b) a localisation, serving-copy or in-country processing duty (e.g., Kenya reg. 26; Rwanda art. 50); (c) a requirement of prior authorisation, notification, licence or registration by a regulator before transfer or storage abroad (e.g., POPIA s. 57(1)(d); NCSA authorisation); (d) sanctions, export-control or national-security screening of the destination or recipient (e.g., US DOJ Data Security Program, 28 CFR Part 202; OFAC) where any Party is a US person or the data concern US persons; (e) a research export permit, ethics-committee export clearance or data-transfer approval required by the origin jurisdiction (e.g., NACOSTI; NHREC); (f) a destination-side import condition (registration, local representative, sectoral hosting certification such as HDS in France).	No	Record the basis for concluding that none applies, with reference to the regime table or Supplementary Data 3. Continue to Step 7(i).

Step	Question	Answer	Required action
6B	Origin-side and destination-side restrictions. Using the Step 6B regime table (and Supplementary Data 3 for jurisdictions not listed), does any of the following apply? (a) a statutory prohibition on transferring this category of data or this type of database (e.g., LGPD art. 13 §2); (b) a localisation, serving-copy or in-country processing duty (e.g., Kenya reg. 26; Rwanda art. 50); (c) a requirement of prior authorisation, notification, licence or registration by a regulator before transfer or storage abroad (e.g., POPIA s. 57(1)(d); NCSA authorisation); (d) sanctions, export-control or national-security screening of the destination or recipient (e.g., US DOJ Data Security Program, 28 CFR Part 202; OFAC) where any Party is a US person or the data concern US persons; (e) a research export permit, ethics-committee export clearance or data-transfer approval required by the origin jurisdiction (e.g., NACOSTI; NHREC); (f) a destination-side import condition (registration, local representative, sectoral hosting certification such as HDS in France).	Unsure	Obtain origin-jurisdiction and destination-jurisdiction review. Do not begin transfer or access. Return to Step 6B when established; if it cannot be established, select Final Decision Outcome 4 below.
7(i)	Exporter side. Under the law of the originating jurisdiction, have the following been identified and documented: the lawful basis or justification for the disclosure; the transfer mechanism indicated at Step 6A (or the reason none is required); the transfer-risk, transfer-impact, privacy-impact or data-protection assessment required for that mechanism or by the origin regime; the authorisations identified at Step 6B; the exporter's authority to make the present transfer or release under any upstream conditions (consent scope, ethics approval, repository or funder terms, community agreements); and the ethics, institutional and repository approvals required? Consider consent or another lawful basis, statutory transfer provisions, adequacy-type mechanisms, contractual safeguards, DPIAs, PIAs or other jurisdiction-specific assessments, regulatory authorisation and institutional approval, as applicable.	Yes	Record each item with its reference and status. Verify the Data Exporter's authority to make the present transfer or release, including applicable upstream conditions. Mark outstanding items as pending. Continue to Step 7(ii).
7(i)	Exporter side. Under the law of the originating jurisdiction, have the following been identified and documented: the lawful basis or justification for the disclosure; the transfer mechanism indicated at Step 6A (or the reason none is required); the transfer-risk, transfer-impact, privacy-impact or data-protection assessment required for that mechanism or by the origin regime; the authorisations identified at Step 6B; the exporter's authority to make the present transfer or release under any upstream conditions (consent scope, ethics approval, repository or funder terms, community agreements); and the ethics, institutional and repository approvals required? Consider consent or another lawful basis, statutory transfer provisions, adequacy-type mechanisms, contractual safeguards, DPIAs, PIAs or other jurisdiction-specific assessments, regulatory authorisation and institutional approval, as applicable.	No or Unsure	Identify the missing basis, mechanism, assessment, approval or evidence of authority. Obtain the necessary origin-jurisdiction legal, ethics, institutional or repository review. Do not begin transfer or access. Return to Step 7(i) when documented. If no applicable lawful pathway can be established, select Final Decision Outcome 4 below.

Step	Question	Answer	Required action
7(ii)	Importer side. Under the law of each receiving, hosting and remotely accessing jurisdiction, have the following been identified and documented: the recipient's own lawful basis or justification for processing (including any special-category, health-data or sensitive-data condition); any registration, notification, licensing, local-representative or data-protection-officer requirement applying to the recipient; any sectoral hosting requirement (for example health-data hosting certification); and the recipient's ethics or institutional approval for the proposed use?	Yes	Record each item with its reference and status. Continue to Step 7A.
7(ii)	Importer side. Under the law of each receiving, hosting and remotely accessing jurisdiction, have the following been identified and documented: the recipient's own lawful basis or justification for processing (including any special-category, health-data or sensitive-data condition); any registration, notification, licensing, local-representative or data-protection-officer requirement applying to the recipient; any sectoral hosting requirement (for example health-data hosting certification); and the recipient's ethics or institutional approval for the proposed use?	No or Unsure	Identify the missing item and obtain destination-jurisdiction review. Do not begin transfer or access. Return to Step 7(ii) when documented; if it cannot be established, select Final Decision Outcome 4 below.
7A	Does the proposed activity require a statutory access authorisation, data permit or research permit under the origin regime or the hosting regime? Examples: a Findata permit (Finland); a Health Data Hub/CESREES authorisation (France); a Forschungsdatenzentrum authorisation (Germany); a Garante authorisation under art. 110 of the Privacy Code (Italy); a NACOSTI permit (Kenya); a UNCST clearance (Uganda); a COSTECH permit (Tanzania); CONEP approval of an international collaboration (Brazil); or, from 26 March 2029, an EHDS data permit.	Yes	Record the competent body, required authorisation, application or approval status, and reference. Record the authorised purpose, users, duration, processing location and release conditions once established. Mark an authorisation not yet obtained as pending; do not begin the activity requiring it. Continue to Step 8.
		No	Record the basis for concluding that no such authorisation is required for this activity. Continue to Step 8.
		Uncertain	Obtain review of the authorisation requirement. Do not begin the affected transfer or access. Return to Step 7A when the requirement is established. If it remains unresolved, select Final Decision Outcome 4 below.
8	Can the receiving or accessing governance environment implement and maintain the safeguards required for the assigned tier? Consider institutional oversight, repository governance, technical controls, contractual compliance, auditability, enforcement and available remedies.	Yes	Record the evidence of capacity to maintain the required safeguards. Identify any safeguards that the environment can support but has not yet implemented, for verification at Step 13. Continue to Step 9.
		No	Record which required safeguards cannot be maintained and why. If an alternative access model or governance arrangement could provide the required protection, select Final Decision Outcome 3 below. If no feasible alternative is identified, select Final Decision Outcome 4 below.

Step	Question	Answer	Required action
		Unsure	Record which safeguards cannot yet be verified. Request evidence from the recipient or provider (policies, certifications, repository governance documents, audit or penetration-test reports, Annexure 5 self-assessment). Do not begin transfer or access until capacity is verified. Return to Step 8 when evidence is available. If evidence cannot be obtained, select Final Decision Outcome 3 where an alternative access model could provide the required protection; otherwise select Final Decision Outcome 4 below.
9	Will the neurodata be linked with additional datasets after transfer or access? Examples include genomic, electronic health-record, wearable-device, consumer or public-register data.	Yes	Record the additional datasets, linkage purpose, responsible party and proposed resulting object. Apply Supplementary Table 6 to the proposed linked dataset or resulting object before linkage begins. Update the tier and safeguards recorded at Step 2 and review Steps 3–8 and 7A against that assessment, revising affected answers. Once the affected checks are complete and no blocking outcome applies, continue to Step 10. Do not repeat the same linkage assessment unless relevant circumstances change.
		No	Record that linkage is outside the assessed arrangement and requires reassessment before introduction. Continue to Step 10.
		Unsure	Record that linkage has not been excluded. Prohibit linkage contractually pending clarification (activate Tool 4 (Supplementary Table 9) Step 12 in its prohibitory form). Obtain confirmation from the recipient. Return to Step 9 when the answer is established; if it remains unresolved at the Final Decision, Outcome 1 may not be selected.
10	Will the neurodata or a derivative artefact be used to train, fine-tune, validate, benchmark or deploy an AI or machine-learning system? Example: An external collaborator will use a transferred EEG dataset to fine-tune a model for detecting cognitive impairment, or use the dataset to validate the performance of an existing predictive model.	Yes	Record the proposed AI activities, system, responsible parties and intended outputs. Complete Tool 3 (Supplementary Table 8) for the proposed activity and follow its Final Decision instructions. If the tier or safeguards change, update Step 2 and repeat the affected pathway checks before continuing. If Tool 3 (Supplementary Table 8) requires unresolved specialist review or prohibits proceeding in the current form, select Final Decision Outcome 4 below. Otherwise, continue to Step 11, carrying forward all outstanding safeguards and restrictions.
		No	Record that these AI activities are outside the assessed arrangement and require assessment before introduction. Continue to Step 11.
		Unsure	Obtain confirmation of the intended AI activities from the recipient. Prohibit unassessed AI use pending clarification. Return to Step 10 when the answer is established. If the intended use cannot be established, select Final Decision Outcome 4 below.

Step	Question	Answer	Required action
11	Will the neurodata be used for a purpose materially different from the approved research purpose? Examples may include commercial development, employment, insurance, clinical deployment or unrelated secondary research where these activities fall outside the already approved purpose, consent, ethics approval or other applicable authorisation. Interpretive note: Assess the proposed purpose against the authorisations and conditions applicable to this activity, including upstream restrictions and relevant consent, ethics and institutional requirements. A purpose different from the original study is not automatically prohibited, and public availability does not automatically authorise it. Record the basis for permitting the proposed use or the additional review or approval required.	Yes	Record the proposed purpose and the gap between it and the approved purpose, the consent, the ethics approval and any upstream condition. Do not begin the new use. Obtain the approvals required under Applicable Law and institutional rules: an ethics amendment; re-consent, or a documented compatibility or secondary-use assessment where the origin regime permits research reuse without re-consent; Data Access Committee approval; and the Data Exporter's written approval. If the proposed purpose is commercial or involves product development, licensing or deployment, mark Tool 4 (Supplementary Table 9) Step 10 as required and Step 11 as not applicable. If the proposed purpose is clinical deployment, record the applicable medical-device or clinical-governance requirements under Tool 4 Step 19. Return to Step 11 when approvals are documented; otherwise select Final Decision Outcome 4 below.
		No	Record the approved purpose and the authorisation or conditions covering it. Continue to Step 12.
		Unsure	Clarify the proposed purpose with the recipient and compare it with applicable authorisations and restrictions. Do not begin the uncertain use. Return to Step 11 when the answer is established. If it remains unresolved, select Final Decision Outcome 4 below.
12	May the recipient disclose, transfer, or provide access to the neurodata or resulting artefacts to another party? This includes collaborators, repositories, vendors, cloud providers, subprocessors and downstream recipients.	Yes	Record permitted onward recipients or recipient categories, purposes and conditions. Check that onward permission is consistent with upstream conditions. Distinguish permission already granted from permission requiring separate approval. Require applicable safeguards to continue throughout the onward pathway and mark outstanding approvals as pending. If the proposed onward arrangement introduces recipients, locations or access modes not yet assessed, update Steps 3–8 and 7A before continuing. Continue to Step 13.
		No	Record and contractually implement the prohibition on onward transfer or access. Continue to Step 13. This prohibition concerns the recipient's onward sharing; authority for the Data Exporter's present transfer remains subject to Step 7.
		Unsure	Clarify the onward-sharing permissions and upstream restrictions. Do not permit onward sharing while permission remains unresolved. Return to Step 12 when the answer is established. If the arrangement cannot be assessed without resolving this issue, select Final Decision Outcome 4 below.
12		Public release recorded at Step 3	Record that onward use is governed by the licence selected at Step 3 and that no further recipient-specific control is possible. Confirm that the licence prohibits re-identification and requires attribution and notification of suspected re-identification. Continue to Step 13.

Step	Question	Answer	Required action
13	Have all legal, institutional, repository, technical and contractual safeguards required for the assigned tier and proposed pathway been implemented and documented? Example: Before an international transfer of Tier 3 MRI data, the parties have confirmed the applicable transfer mechanism and approvals, implemented encrypted transfer and role-based access, enabled audit logging, restricted onward sharing, and documented permitted uses, retention, deletion and incident-response requirements.	Yes	Record the implementation evidence and responsible verifier. Proceed to the Final Decision below and check the conditions for Outcome 1. Outstanding requirements identified earlier must still be satisfied.
		No, but they can be implemented.	Record each outstanding safeguard, the responsible party and the evidence needed to verify implementation. Proceed to the Final Decision below and select Outcome 2 only if its conditions are met. Do not begin transfer or access before implementation is verified.
		No, and they cannot be implemented within the proposed pathway	Record the safeguards that cannot be implemented. Select Outcome 3 if a feasible alternative arrangement may provide the required protection. Otherwise, select Final Decision Outcome 4 below.
		Unsure	Obtain verification from the responsible technical, legal or governance reviewer. Do not begin transfer or access. Return to Step 13 when implementation can be established. If material uncertainty remains, select Final Decision Outcome 4 below.
<i>Final Decision: Select and document one outcome Interpretive note: A Neuro-TADT outcome provides structured governance decision support. It does not independently authorise processing, establish formal legal adequacy or replace any required legal, ethics, institutional, repository or regulatory determination.</i>			
	Outcome	Decision Criterion	

Step	Question	Answer	Required action
1	Proceed subject to applicable approvals	Select only where the applicable lawful basis, transfer or access mechanism, required approvals and authority for the present transfer have been confirmed, and all required safeguards are implemented and documented. Record the approved recipients, purposes, access conditions, supporting evidence and reviewer. Proceed only within those confirmed approvals and conditions. Reassess before a material change to the object, purpose, recipient, jurisdiction or access arrangement. Outcome 1 may not be selected while any Step 6B prerequisite, Step 7(i)/(ii) item or Step 9 uncertainty remains open. For public release, Outcome 1 additionally requires the Tier 1/1b or model-anonymity condition at Step 3 to be confirmed, the licence to be recorded, and a takedown and re-identification-response procedure to be documented.	

Step	Question	Answer	Required action
2	Proceed after supplementary safeguards are implemented	Select where the applicable legal and approval prerequisites are established, but specified safeguards remain to be implemented within the current pathway. Record each outstanding safeguard, responsible party and verification requirement. Withhold transfer or access until implementation is verified. Return to Step 13 and, if all conditions are satisfied, record Outcome 1.	
3	Redesign the transfer or access pathway	Select where required safeguards cannot be maintained under the current arrangement but a feasible alternative may provide the required protection. Record why the current pathway is unsuitable and the proposed changes. Do not begin transfer or access through the unsuitable pathway. Repeat this Tool for the redesigned arrangement, updating Supplementary Table 6 if the changes could affect functional exposure or the required tier.	

Step	Question	Answer	Required action
4	Do not proceed and obtain specialist review	Select where a required legal basis, mechanism, approval, recipient identity or material governance issue remains unresolved, or the required protection cannot be maintained. Record the reason, required review and responsible person or body. Do not begin the affected transfer or access. Following review, return to the affected step and update all dependent answers. If no acceptable pathway is established, retain this outcome.	

Tool 3 — Derivative and Embedding Governance Decision Tool

Supplementary Table 8

Assesses whether technical transformation (features, embeddings, synthetic data, predictions, trained models) has materially changed functional exposure and whether the tier or safeguards require reassessment. Step 7 holds the leakage and anonymity assessment that gates public release of models. Produces five outcomes.

Step	Question	Answer	Required action
1	Has the neurodata undergone, or will it undergo, technical transformation; will it be used in an AI or machine-learning system; or may neurodata-derived information persist in a model or computational infrastructure? Apply the triggers and exceptions in Annexure 1 §7.2. Examples include feature extraction, dimensionality reduction, embedding generation, predictive modelling, synthetic-data generation or AI-model training.	No	Record why none of these triggers applies. Retain the tier and safeguards established under Tool 1 / Supplementary Table 6. Record "Tool 3 (Supplementary Tool 8) not required for this activity" and return to the referring Tool at its next applicable step. Reassess if the activity or object changes.
		Yes	Record the applicable trigger. If an exception under Annexure 1 §7.2 is established for this particular object and activity, document the exception and return to the referring Tool. Do not apply that exception to AI activities requiring assessment under Supplementary Table 7 Step 10. Otherwise, continue to Step 2.
		Unsure	Obtain clarification of the processing, AI activity or possible computational persistence. Do not mark the activity as exempt while applicability remains uncertain. Pause this assessment and return to Step 1 when the answer is established.
2	What form of transformation has occurred or is proposed? Examples include feature vectors, embeddings, connectivity measures, reconstructed signals, classifiers, predictions, synthetic neurodata, trained models, model gradients, or other derived representations.	One or more forms or activities identified	Record the transformation or activity, purpose, source neurodata, technical method and resulting or assessed artefact. Identify its version and any retained intermediate representations requiring separate assessment. Continue to Step 3.
		Other, but sufficiently described	Describe the activity and artefact in technical terms sufficient to assess exposure, even if no listed category fits. Continue to Step 3.
		Unclear	Obtain a description from the technical lead, recipient or provider. Pause progression until the activity and assessed object can be identified. Return to Step 2. If essential information cannot be obtained, select Final Decision Outcome 4 below.
3	Can the resulting artefact circulate, be accessed, queried or be deployed independently of the source neurodata? Example: a trained model, embedding repository or predictive classifier is shared without distributing the original EEG or MRI dataset.	Yes	Record the intended recipients, access mechanisms and deployment environment. Identify the controls needed when the artefact is used without the source data. Continue to Step 4. Independent circulation does not itself determine a tier.
		No	Record how the artefact remains connected to, or controlled with, the source neurodata. Continue to Step 4.
		Unsure	Record independent circulation as possible pending technical confirmation. Request confirmation of the architecture and access arrangements. Continue to Step 4, retaining the unresolved issue for the Final Decision.

Step	Question	Answer	Required action
4	Can the resulting artefact, alone or with information reasonably available to the intended recipient, identify or trace a participant or re-establish linkage to the source neurodata? Examples: an embedding or latent representation unique to a participant; a synthetic dataset that reproduces training records; a model that memorises participant-level signals; outputs that carry source identifiers or acquisition metadata.	Yes	Record the identification or tracing mechanism and supporting evidence. Flag the finding for classification under Tool 1 / Supplementary Table 6 and retain applicable identification and linkage safeguards. Continue to Step 5; do not determine the final tier from this answer alone.
		No	Record the supporting evidence and the additional information considered. Continue to Step 5. Absence of identification does not establish absence of inference or computational persistence.
		Unknown	Record the unresolved identification or linkage question and request technical assessment. Apply the relevant provisional safeguards under Tool 1 / Supplementary Table 6. Continue to Step 5 and retain the uncertainty for the Final Decision.
5	Can the artefact reveal, predict, reconstruct or profile neurological, cognitive, emotional or behavioural characteristics of an individual or group, even without directly identifying a participant? Distinguish ordinary aggregate description from material group-level Functional Exposure under Annexure 1 §2.1. Example: an EEG-derived embedding predicts cognitive decline, or a model output classifies stress, attention or neurological status.	Yes	Record the capability, affected individuals or group, supporting evidence and relevant access conditions. Record a candidate Tier 4 condition and apply Tier 4 safeguards provisionally, retaining any higher applicable safeguards. Continue to Step 6.
		No	Record the evidence supporting this conclusion and its limitations. Continue to Step 6.
		Unknown	Record the unresolved inferential, reconstructive or profiling capability. Apply provisional Tier 4 safeguards, retaining any higher applicable safeguards. Request the technical assessment needed to resolve the question. Continue to Step 6.
6	Has neural information become, or may it reasonably have become, computationally persistent within a model, shared embedding, model gradient, synthetic-data generator, or other infrastructure in a manner capable of supporting continuing inference, reconstruction, extraction or profiling? Model incorporation alone is not sufficient; consider whether information derived from the neurodata may persist and create continuing functional exposure.	Yes	Record a candidate Tier 5 condition and the evidence of continuing functional exposure. Apply Tier 5 safeguards provisionally pending completion of the assessment. Continue to Step 7. Confirm Tier 5 only if the completed assessment meets Outcome 3.
		No	Record the technical evidence supporting the absence of continuing computational exposure and its limitations. Do not assign Tier 5 solely because model incorporation occurred. Continue to Step 7.
		Unknown	Record provisional Tier 5 and the unresolved persistence or exposure question. Apply Tier 5 safeguards provisionally and request specialist assessment. Continue to Step 7. If material uncertainty remains at the Final Decision, select Outcome 4 rather than confirming Tier 5.

Step	Question	Answer	Required action
7	Has the artefact or model been evaluated, where technically relevant, for memorisation, training-data extraction, model inversion, membership inference or other forms of information leakage, under the intended access and release conditions? Where public or unrestricted release is proposed, apply the anonymity assessment: (1) likelihood of direct extraction of participant-level information from the artefact (weights, embeddings, generator); (2) likelihood of obtaining participant-level information through queries or outputs, considering all means reasonably likely to be used by any member of the public; (3) documentation of the methods, thresholds, versions and residual risk (cf. EDPB Opinion 28/2024). Example: testing assesses whether prompts, queries or attacks can recover participant-related neural information or determine whether particular records contributed to model training.	Yes—material exposure was identified	Record the methods, findings, artefact version and tested access conditions. Update the findings at Steps 4–6 as indicated by the evidence. Record a candidate Tier 5 condition where leakage demonstrates continuing model-associated or computationally persistent exposure. Continue to Step 8. Record 'Public release not supported'.
		Yes—no material exposure was identified	Record the testing scope, methods, thresholds, artefact version and access conditions. Where the tested conditions include public release and steps (1)–(3) are documented, record 'Anonymity assessment documented: public release may be considered at Tool 2 (Supplementary Table 7) Step 3'. Do not treat the result as proof of absence of exposure beyond those conditions or automatically remove an earlier finding. Continue to Step 8.
		Not tested or unknown	Obtain a technical assessment of whether testing is relevant, proportionate and feasible. Record required testing or alternative evidence, the responsible person and any remaining uncertainty. Retain applicable provisional safeguards and continue to Step 8. If material exposure cannot be assessed reliably, select Outcome 4 at the Final Decision. Record 'Public release not supported'.
		Not technically applicable	Record the technical justification and responsible reviewer. Continue to Step 8. This answer does not resolve other exposure findings. Record 'Public release not supported'.
8	Are the provenance and transformation history of the artefact sufficiently documented? Consider the source neurodata, lawful provenance, preprocessing, training purpose, model architecture, training or fine-tuning procedure, model version, vendors, cloud providers, sub processors and subsequent modifications.	Yes	Preserve or reference the provenance and version records. Continue to Step 9.
		No	Identify the missing records and request them from the responsible parties. Record whether each gap affects the assessment or proposed use. Continue to Step 9, carrying unresolved gaps to the Final Decision. Do not approve affected sharing or deployment while essential provenance remains unresolved.
		Unknown	Obtain information from the technical team, recipient, vendor or provider. Record the outstanding provenance questions and responsible person. Continue to Step 9, carrying unresolved gaps to the Final Decision.

Step	Question	Answer	Required action
9	Will the proposed access or deployment conditions materially affect functional exposure? Consider downloadable copies, public release, API or query access, external hosting, fine-tuning, transfer learning, model merging, distillation, commercial deployment or access by additional recipients.	Yes	Record the conditions, their effect on exposure and the safeguards required. Revisit Steps 4–7 if those conditions change the evidence supporting an answer. Mark Supplementary Table 7 for completion or update where an external transfer or access pathway is involved. Continue to Step 9A
		No	Record the assessed access and deployment conditions and why they do not materially change exposure. Continue to Step 9A.
		Unknown	Obtain clarification of intended access, hosting and deployment. Do not approve the unresolved arrangement. Return to Step 9 when the conditions are established. If material uncertainty remains, select Final Decision Outcome 4.
9A	Have the proposed outputs, including features, embeddings, synthetic outputs, and model weights, been assessed against applicable authorisation and release conditions?	Yes	Record the assessment, applicable conditions, responsible reviewer and approval status. Mark outstanding approvals as pending and withhold release until required approvals are obtained. Continue to Step 10.
		No	Identify the required output or release assessment and responsible reviewer. Withhold release pending that assessment and any required approval. Continue to Step 10 with the requirement recorded as outstanding.
		Uncertain	Obtain confirmation of the applicable conditions and whether they have been assessed. Withhold release while unresolved. Continue to Step 10, retaining the uncertainty for the Final Decision.
10	Are retention, withdrawal, deletion, decommissioning and, where technically feasible, model-unlearning procedures documented and capable of implementation? Example: the project specifies how model versions and embeddings will be retained, how access will be terminated, whether derived artefacts can be deleted and what alternative controls will apply if reliable unlearning is not technically feasible.	Yes	Record the applicable triggers, responsible parties, procedures, timeframes and verification requirements. Assess the effects of EHDS opt-out, consent withdrawal, erasure requests and contractual termination separately, including their implications for previously authorised processing. Continue to Step 11.
		Partly	Record unavailable controls and their consequences. Obtain review of proportionate alternatives, such as access withdrawal, version retirement, decommissioning, output restrictions or prohibition of further training. Record accepted alternatives, outstanding implementation actions and responsible parties. Continue to Step 11. Do not treat a proposed alternative as an implemented safeguard.
		No or unknown	Obtain specialist technical and governance review of the limitations and possible alternative safeguards. Withhold external sharing or deployment pending that review. Continue to Step 11 with the review requirement recorded as outstanding.

Step	Question	Answer	Required action
11	Can the identified functional exposure be managed through proportionate legal, institutional, repository, technical and contractual safeguards throughout the proposed use and deployment? Example: An fMRI-derived predictive model remains capable of neurological inference, but access is limited to approved researchers within a secure environment; queries and outputs are monitored; unauthorised profiling, retraining and onward sharing are contractually prohibited; and audit, incident-response, retention and model-decommissioning procedures are documented and enforceable.	Yes	Record the safeguards and supporting assessment. Proceed to the Final Decision. Any unresolved issue from an earlier step remains applicable.
		Only after additional safeguards	Record each safeguard, responsible party and implementation evidence required. Proceed to the Final Decision, identifying any suitable tier outcome separately from outstanding implementation conditions. Do not begin the affected activity until the required safeguards are implemented and verified.
		Unsure	Record the unresolved governance question and required review. Select Final Decision Outcome 4.
		No	Record why the exposure cannot be managed under the proposed arrangement. Select Final Decision Outcome 5.
<i>Final Decision: Select and document one outcome Reassessment and implementation: If the assessment changes the provisional tier, return to the Neurodata Governance Decision Tool (Supplementary Table 6). If it affects an existing or proposed transfer or access pathway, repeat the Neurodata Transfer and Access Decision Tool (Supplementary Table 7). The resulting governance determinations should then be implemented through the MDTAA Clause Selection Tool (Supplementary Table 9) where contractual governance is required.</i>			
	Outcome	Decision criterion and required action	

Step	Question	Answer	Required action
1	Retain the existing Tier	Select where documented evidence supports the existing classification of the assessed artefact, no new or increased exposure requires a higher tier, and the applicable safeguards remain suitable. Record the tier, supporting evidence, limitations and any outstanding implementation conditions. Do not convert a candidate or provisional tier into a confirmed tier through this outcome. Resolve material classification uncertainty through Outcome 4. If returning to an unfinished Tool 1 / Supplementary Table 6 assessment, resume at its next applicable step and complete Steps 5 and 6. Complete or update Tool 2 / Supplementary Table 7 where an external pathway is involved.	

Step	Question	Answer	Required action
2	Refer for Tier 4 classification / re-assessment	Select where a derived artefact supports identification, tracing or material inference, reconstruction or profiling consistent with Table 6 Step 4, and the assessment provides sufficient evidence that Tier 5 criteria are not met. Record the evidence and apply Tier 4 safeguards provisionally. Return to Tool 1 / Supplementary Table 6 at Step 3, follow the Tier 4 pathway and complete Steps 5 and 6. Document resolution of any candidate or provisional Tier 5 finding addressed by this assessment. Absence of evidence alone does not resolve material uncertainty. Do not automatically lower a previously confirmed Tier 5: apply the documented reassessment and approval requirements in Annexure 3 §10.3. Complete or update Tool 2 / Supplementary Table 7 using the resulting classification and safeguards where an external pathway is involved.	

Step	Question	Answer	Required action
3	Confirm Tier 5 classification	Select where the completed assessment demonstrates continuing functional exposure through neural information persisting within a model or computational infrastructure. Model incorporation alone is insufficient. Record the evidence and confirm Tier 5 finding. Return to Tool 1 / Supplementary Table 6 at Step 2B, record Tier 5 as confirmed and continue from Step 3, including Steps 5 and 6, to identify cumulative safeguards. Reference this completed Tool 3 / Supplementary Table 8 assessment; do not restart it solely because Tool 1 / Supplementary Table 6 refers to it. Complete or update Tool 2 / Supplementary Table 7 where an external pathway is involved.	

Step	Question	Answer	Required action
4	Specialist review required	Select where material questions about exposure, persistence, testing, provenance, authorisation conditions, deployment or lifecycle controls remain unresolved. Record each unresolved question, required evidence and responsible reviewer. Retain the applicable protective provisional tier and safeguards. Where continuing computational exposure remains materially uncertain, retain provisional Tier 5 safeguards. Do not begin the activity that depends on resolution of the outstanding issue. Following review, return to the affected step, update dependent answers and reconsider the Final Decision.	

Step	Question	Answer	Required action
5	Do not proceed in the current form	Select where exposure cannot be managed proportionately, essential provenance or oversight cannot be obtained, required lifecycle controls or acceptable alternatives cannot be implemented, or the proposed activity cannot satisfy applicable conditions. Record the reasons and retain the assessment and established tier findings. Do not commence or continue the affected activity in its assessed form. If the artefact, model, access arrangement or purpose is redesigned, repeat the affected assessments before proceeding.	

Tool 4 — MDTAA Clause Selection Tool

Supplementary Table 9

Maps the outcomes of Tools 1–3 to the modules of the Modular Neurodata Transfer and Access Agreement, including the transfer-instrument module for the origin regime. Module selection does not establish lawfulness or enforceability.

Step	Scientist-facing question	If YES	If NO
1. Baseline governance module	Is the MDTAA being used to govern the processing, access, transfer or reuse of neurodata or a governed derivative artefact? Example: A university intends to provide an external collaborator with controlled access to coded EEG recordings under an MDTAA.	Activate the Baseline Governance Module. Identify the parties, assessed objects and activities governed by the arrangement. Continue to Step 2 (Articles 3–7, 9–10 and 14–17; Schedules A and B; Annexure 4, section 5.1.)	Record "MDTAA Clause Selection Tool not applicable". Identify whether another agreement or governance mechanism is required. End this Tool.
2. Cross-Border Transfer Module	Does the arrangement involve international transfer, storage in another jurisdiction or remote access from another legal jurisdiction? Example: MRI data collected in South Africa will remain on a South African server but will be accessed remotely by researchers in Germany.	Activate the Cross-Border Transfer Module. Record the originating, receiving, hosting and remotely accessing jurisdictions, the pathway class from Tool 2 (Supplementary Table 7) Step 6A and the restrictions recorded at Step 6B. Activate the Transfer-Instrument Module corresponding to the origin regime (MDTAA Part III: T-EU, T-UK, T-CH, T-BR, T-AR, T-ZA, T-NG, T-KE, T-RW, T-CA, T-US or T-GEN) and record the mandatory instrument in Schedule A Part E.5. Continue to Step 3. (Core Articles 12, 13 and 13A; the activated Transfer-Instrument Module; Annexure 2; Schedule C, where applicable.)	Do not activate this module on the basis of this step. Continue to Step 3.

Step	Scientist-facing question	If YES	If NO
3. Supplementary Safeguards Module	Did the Neuro-TADT identify supplementary safeguards as a condition for proceeding? Examples include enhanced encryption, controlled access, local storage, additional oversight or restrictions on government access.	Activate the Supplementary Safeguards Module. Specify each safeguard identified by Tool 2 / Supplementary Table 7, the responsible party and the evidence required to verify implementation. Continue to Step 4. (Article 13A; Schedule C; relevant Annexures as identified by the Neuro-TADT).	Retain the baseline safeguards and all other safeguards required by the preceding assessments. Continue to Step 4.
4. Enhanced Neurodata Protection Module	Does Tool 1 / Supplementary Table 6 assessment require Tier 3, Tier 4 or Tier 5 safeguards, whether under a confirmed classification or provisionally pending further assessment? Example: Raw intracranial recordings containing persistent participant and device identifiers have been classified as Tier 3 and require enhanced access, security and accountability controls.	Activate the Enhanced Neurodata Protection Module. Incorporate the safeguards required for the applicable Tier 3, Tier 4 or Tier 5 classification, retaining safeguards associated with other conditions that remain present. Mark the selection as provisional where the classification remains provisional. Continue to Step 5. (Articles 10A and 11A; Annexure 1; Annexure 5; Schedule B-D, where applicable).	Retain the safeguards required for the applicable tier and any separately identified conditions. Continue to Step 5.

Step	Scientist-facing question	If YES	If NO
5. Derivative Neurodata Module	Does the arrangement involve features, embeddings, connectivity measures, predictions, reconstructed signals, synthetic neurodata or other transformed neural representations? Example: The recipient will generate and retain fMRI-derived embeddings and functional-connectivity measures rather than receiving only the original imaging dataset.	Activate the Derivative Neurodata Module. Specify the governed artefacts, permitted transformations and uses, access conditions and prohibited activities. Incorporate applicable findings from Tool 3 / Supplementary Table 8 or reference the documented exception under Annexure 1 §7.2. Continue to Step 6. (Article 10B; Annexure 3; Article 11B where deletion or unlearning is implicated.)	Do not activate this module on the basis of this step. Continue to Step 6.
6. AI and Model Governance Module	Will neurodata or derivative artefacts be used to train, fine-tune, validate, benchmark, query or deploy an AI or machine-learning system? Example: An external research team will use EEG recordings to fine-tune and validate a machine-learning model for predicting cognitive impairment.	Activate the AI and Model Governance Module. Specify authorised AI activities, systems or models, technical environments, access restrictions and oversight requirements. Incorporate applicable conditions from Tools 2 and 3 / Supplementary Tables 7 and 8. Module selection does not itself establish Tier 5. Continue to Step 7. (Article 6A; relevant provisions in Schedule D where applicable).	Do not activate this module on the basis of this step. Continue to Step 7.

Step	Scientist-facing question	If YES	If NO
7. Controlled Access, Repository and Infrastructure Module	Will access or processing occur through a repository, secure enclave, trusted research environment, federated system, cloud platform, vendor environment or other controlled infrastructure? Example: Researchers will analyse participant-level MRI data inside a trusted research environment that permits approved queries but prohibits downloading the underlying data.	Activate the Controlled Access, Repository and Infrastructure Module. Specify the infrastructure, access model, administrators, providers, security controls and output or download restrictions. Continue to Step 7A. (Articles 6B, 10A, 10B, and 13A; Annexures 2 and 5; Schedules C and D, where applicable.)	Do not activate this module on the basis of this step. Continue to Step 7A.
7A. Statutory Access Conditions	Does the arrangement operate under an EHDS permit or another statutory authorisation?	Record the statutory authorisation, its status and its applicable conditions in Schedules C and D, as relevant. Identify the selected provisions that implement each condition; use Step 19 for any additional provisions required. Record any pending authorisation or unresolved condition as outstanding. Continue to Step 8.	Reference the determination made under Tool 2 / Supplementary Table 7 Step 7A that no such authorisation is required. Continue to Step 8.
8. Onward Transfer and Sub-Processor Module	May the recipient appoint sub-processors or provide the neurodata, derivatives or model-associated artefacts to additional recipients? Example: The receiving university proposes to use a cloud provider for processing and to share derived embeddings with another consortium partner.	Activate the Onward Transfer and Subprocessor Module. Specify permitted recipients or recipient categories, purposes, approval conditions and safeguards that must continue throughout the onward arrangement. Distinguish existing permission from permission requiring further approval and check consistency with upstream conditions. Continue to Step 9. (Article 8; SCC Annex III where applicable).	Record that onward transfer or appointment of sub-processors is not permitted under the assessed arrangement. Continue to Step 9 to specify the applicable prohibition and any approval procedure.

Step	Scientist-facing question	If YES	If NO
9, No Onward Transfer Module	Must onward transfer, third-party access, subcontracting, cloud replication or redistribution be prohibited unless prior approval is obtained? Example: The recipient may analyse the EEG data internally but may not upload it to another repository, engage a new cloud vendor or share it with another collaborator without prior written approval.	Activate the No Onward Transfer Module. Specify the prohibited activities and any expressly permitted exceptions or prior-approval procedure. Reconcile these restrictions with Step 8 so that permitted onward activities and prohibited activities are clearly distinguished. Continue to Step 10. (Articles 8).	Confirm that any permitted onward activities and their conditions have been addressed at Step 8. If Step 8 was also answered "No", clarify the onward-sharing position and revise Step 8 or Step 9 before continuing. Continue to Step 10.
10. Commercial Use and Intellectual Property module	Does the arrangement involve a commercial partner, product development, licensing, intellectual-property generation or another anticipated commercial use? Example: A medical-device company will use transferred neurodata to develop and commercialise an algorithm for detecting neurological deterioration.	Activate the Commercial Use and Intellectual Property Module. Specify permitted commercial activities, if any, together with ownership, licensing, publication and benefit-allocation conditions. Do not treat the involvement of a commercial partner or the creation of intellectual property as permission for commercial use. Continue to Step 11. (Article 3A; Schedule B where applicable).	Do not activate this module on the basis of this step. Continue to Step 11.

Step	Scientist-facing question	If YES	If NO
11. Research Use Only Module	Must use of the neurodata and resulting artefacts be restricted to the approved non-commercial research purposes? Example: A university consortium may use the data only for the approved academic study and may not use them for product development, commercial licensing, employment screening or insurance assessment.	Activate the Research Use Only Module. Specify the approved non-commercial research purposes, authorised users and prohibited uses. Check consistency with Step 10. Where both modules apply, ensure that intellectual-property or commercial-partner provisions do not authorise prohibited commercial use. Continue to Step 12. (Articles 3–6 and 10; incorporated SCC purpose-limitation provisions; Schedules A and B; Schedules C and D, where applicable.)	Do not activate the Research Use Only Module. Specify the other authorised purposes and applicable restrictions; this answer does not permit unrestricted use. Continue to Step 12.
12. Dataset Linkage Module	Will the neurodata be linked with genomic, clinical, behavioural, wearable, consumer, administrative, public-register or other datasets? Example: Pseudonymised EEG recordings will be linked with genomic variants and electronic health records to investigate predictors of neurodegenerative disease.	Activate the Dataset Linkage Module. Specify authorised datasets, linkage purposes, responsible parties, reassessment requirements and restrictions on further linkage. Incorporate the classification and pathway requirements identified through Tool 2 / Supplementary Table 7 Step 9 and the resulting Table 6 assessment. Continue to Step 13. (Article 4.2(b); Articles 10A and 10B; Annexure 1, section 6.1(a); Annexure 2, sections 7.1(j) and 8.1(f); Annexure 3, sections 7(e) and 10.1(e); Schedule B, Parts B–D and I; Schedule C, Parts H–I and K; Schedule D, Part H, where applicable.)	Record that dataset linkage is outside the assessed arrangement and requires reassessment before introduction. Continue to Step 13.

Step	Scientist-facing question	If YES	If NO
13. Permitted Inference and Prohibited Use Module	Can the neurodata or governed artefact support sensitive inference, reconstruction or profiling, or are particular inferences or uses required to be prohibited? Examples include cognitive profiling, emotional inference, reconstruction of neural activity, employment screening or insurance use. Example: The approved project permits inference concerning cognitive fatigue but prohibits emotional profiling, employment screening, insurance assessment and reconstruction of unrelated mental states.	Activate the Permitted Inference and Prohibited Use Module. Specify authorised analyses, prohibited inferences and decisions, and output-review requirements. Distinguish technically possible activities from activities that are authorised. Continue to Step 14. (Article 3A; Articles 6A, 10.6, 10A and 10B; Annexure 1, sections 2–4; Annexure 3, sections 7–8 and 12; Schedule B, Parts C and I; Schedule C, Parts H–I; Schedule D, Parts D–E, where applicable.)	Retain baseline purpose limitations and all existing use restrictions. Continue to Step 14.
14. Enhanced Audit and Monitoring Module	Do the assigned tier, Neuro-TADT outcome, AI use, recipient environment or identified uncertainty require enhanced audit, monitoring or incident reporting? Example: Access to a Tier 5 model must be logged continuously, with quarterly access reviews, documented model-version changes and immediate reporting of attempted extraction or inversion attacks.	Activate the Enhanced Audit and Monitoring Module. Specify logging, reporting, inspection, testing and audit requirements, including frequency and responsible parties. Continue to Step 15. (Articles 6, 6A.9, 13A and 15; Annexure 2, sections 6–8; Annexure 3, sections 7–10; Annexure 5; Schedule C, Parts I and K; Schedule D, Parts F and H, where applicable.)	Retain baseline audit, monitoring and incident-reporting obligations. Continue to Step 15.

Step	Scientist-facing question	If YES	If NO
15. Return, Deletion and Certification Module	Must neurodata, copies or derivative artefacts be returned, deleted or certified as destroyed at the end of the project, following withdrawal or after another specified event? Example: At project completion, the recipient must delete all local EEG copies and derived feature files and provide written certification of deletion within 30 days.	Activate the Return, Deletion and Certification Module. Specify the objects and copies covered, applicable triggers, timeframes, responsible parties, verification evidence and permitted archival exceptions. Continue to Step 16 to address any retained model or persistent artefact separately. (Article 6 and incorporated SCC Clause 8.5; Articles 10, 11B and 15; Annexure 3, sections 7–10; Annexure 5; Schedule B, Parts D and I; Schedule C, Parts I and K; Schedule D, Parts G–H, where applicable.)	Record the authorised retention period, purpose and applicable conditions. Do not treat this answer as permission for indefinite retention or as displacing mandatory deletion obligations. Continue to Step 16.
16. Persistent Artefact, Model Retention and Unlearning Module	Does the arrangement involve a model, embedding or computational artefact that may persist after the source neurodata are deleted, returned or withdrawn? Example: A predictive model trained on participant neurodata will remain operational after the source dataset is deleted, requiring documented model-retention, version-retirement, decommissioning and technically feasible unlearning procedures.	Activate the Persistent Artefact, Model Retention and Unlearning Module. Specify retention, version retirement, access withdrawal, decommissioning, deletion and technically feasible unlearning procedures, including approved alternatives where necessary. Reconcile these provisions with Step 15 and the findings of Table 8. Continue to Step 17. (Articles 6A, 10B and 11B; Annexure 1, section 3.5; Annexure 3, sections 8–10; Schedule B, Parts H–I; Schedule C, Parts G–I and K; Schedule D, Parts E, G and H, where applicable.)	Do not activate this module on the basis of this step. Continue to Step 17.

Step	Scientist-facing question	If YES	If NO
17. Community, Collective and Indigenous Data Governance Module	Does the project involve an Indigenous community, defined population, patient group or other collective with relevant governance authority, cultural interests or community-approved conditions? Example: Neuroimaging data were collected from an Indigenous community whose recognised governance body requires continuing approval of secondary uses and representation on the data-access committee.	Activate the Community, Collective and Indigenous Data Governance Module. Specify the relevant governance body or representatives, consultation requirements, permissions, access conditions and continuing governance arrangements. Continue to Step 18. (Article 3A; Articles 5A and 9, where applicable; Schedule A, Parts A–D; Schedule B, Part I; Schedule D, Part B, where a Data Access Committee exercises continuing authority; Annexure 4, section 5.17.)	Do not activate this module on the basis of this step. Continue to Step 18.
18. Benefit Sharing and Capacity Development Module	Does the arrangement require benefit-sharing, local analytical access, training, infrastructure support, co-authorship, technology transfer or other capacity-development commitments? Example: An international collaborator receiving neurodata from a lower-resourced institution must provide local researchers with analytical training, access to computing infrastructure, opportunities for co-authorship and participation in downstream model development.	Activate the Benefit Sharing and Capacity Development Module. Specify the commitments, beneficiaries, responsible parties, timeframes and evidence of fulfilment. Continue to Step 19. (Article 3A; Schedule A, Parts A–B; Schedule B, Part I; Annexure 4, sections 5.10, 5.17 and 5.18, as applicable.)	Do not activate this module on the basis of this step. Continue to Step 19.

Step	Scientist-facing question	If YES	If NO
19. Optional Project- Specific Module	Are additional jurisdictional, institutional, funder, community or project-specific requirements not addressed adequately by the preceding modules? Examples include export controls, device regulation, cybersecurity certification, publication review or specialised funder conditions. Example: A brain–computer interface project must comply with medical-device requirements, cybersecurity certification conditions and a funder obligation requiring public release of specified aggregate findings.	Activate the Optional Project-Specific Module. Specify requirements not adequately addressed by the other selected modules, including any outstanding implementation provisions identified at Step 7A. Identify the source of each requirement and how it relates to the other MDTAA provisions. Continue to Step 20. (Articles 4–5 and 18; Schedules A–D; relevant Annexures and SCC Annexes I–III, as applicable; Annexure 4, section 5.19.)	Do not activate this module. Continue to Step 20.
20. Contract ual Coordina tion and Precede nce Module	Will the MDTAA operate alongside other legal or governance instruments? Examples include Standard Contractual Clauses, a Data Use Agreement, repository terms, institutional agreements, cloud contracts or funder conditions. Example: The transfer is governed simultaneously by the MDTAA, European Union Standard Contractual Clauses, a repository-access agreement, an institutional Data Use Agreement and the recipient’s cloud-services contract.	Activate the Contractual Coordination and Precedence Module. Identify the other governing instruments, applicable mandatory requirements and the procedure for resolving inconsistencies. Record relevant expiry or termination dates and surviving permissions or obligations. Refer proposed retention, reuse, onward transfer or model persistence beyond those dates for review where required; do not presume that expiry automatically ends all downstream permissions or obligations. Proceed to Final Decision and Implementation. (Articles 3B, 18 and 19; Schedules A–D; SCC Annexes I–III, where incorporated; Annexure 4, sections 2.7 and 5.20.)	Record the basis for concluding that no additional governing instrument applies. Confirm that the MDTAA remains consistent with applicable mandatory law and institutional requirements. If another governing instrument is identified, revise this answer to “Yes”. Proceed to Final Decision and Implementation.

Step	Scientist-facing question	If YES	If NO
<i>Final Decision and Implementation: After completing Steps 1–20 Interpretive note: Selection of an MDTAA module does not establish that the underlying processing or transfer is lawful or that the resulting agreement is enforceable in every jurisdiction. Applicable mandatory law and authorised legal, regulatory, ethics, institutional and repository determinations continue to govern.</i>			
1. Compile and record	Compile the Baseline Governance Module and all additional modules selected. Record each selection, its trigger, the responsible party and the provisions implementing it. Complete the relevant schedules, annexures and project-specific fields.		
2. Check consistency	Check the selected provisions against Tables 6–8 and other applicable instruments. Resolve conflicting permissions or restrictions, particularly between Steps 8–9, 10–11 and 15–16. Return to the relevant assessment or selection step where clarification is required.		
3. Review and finalize	Obtain required legal, ethics, institutional, repository or regulatory review. Do not finalise or execute the MDTAA while mandatory review or another prerequisite remains unresolved. Record the approved agreement version and outstanding implementation conditions.		
4. Implement and reassess	Do not commence the relevant activity until required approvals and safeguards are in place. Reapply the affected assessments and module-selection steps when material changes alter the object, tier, purpose, recipients, jurisdictions, infrastructure, access arrangements or required safeguards.		

