

DATA BANK PROTOCOL INSTRUCTIONS

- If the data bank is part of a protocol, meaning it will include data only from the ONE currently submitted protocol, then the data banking protocol can be submitted as part of the initial application for that protocol or as an amendment to an existing protocol. The databank would be described within the Participants/Privacy & Confidentiality section of the IDEATE application.
- If the data bank is a separate bank that will include data from multiple studies, the data banking protocol should be a stand-alone protocol. Information being requested below are for Principal Investigators submitting a standalone Databank Protocol. If investigators would like examples of standalone databank protocol submissions, please contact [ORCO Staff](#).

The data banking protocol/application should address the following:

- Purpose of the data bank
- Data points that will be included in the data bank
- Whether the data will be banked with subject identifiers, with codes, or without either
 - If with identifiers, list the identifiers
 - with codes, who will have access to the links and where will the links be stored
- Whether the data will be shared with subject identifiers, with codes, and/or without either
- Describe the process by which data may be requested by other researchers
 - If the data bank will use a data request form, please attach
 - Identify individual(s) responsible for determining the adequacy of the requests
- Describe the mechanism for determining if subjects whose data is included in the data bank provided informed consent for future use of their data for the purposes of this bank
 - If subjects did not give consent, please provide an explanation for why not (this may be study specific)
- Who will collect the data/samples?
- Where and how will the data/samples be collected?
- Where will the data/samples be stored?
- How will confidentiality be maintained?
- Are the data/samples coded/encrypted?
- Do the data/samples contain identifiers? Are they coded?
- Will the data/samples be shared? Will other researchers be able to use the data/samples? Will they be shared with identifiers or codes? If sharing, who will approve request for sharing? Will there be a form for requesting data/samples?

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- Does the consent form adequately describe all the possible uses of the data/samples? Are there checkboxes that allow the subject to agree to future use of their data/samples? Are there checkboxes that allow the subject to decide what specific protocols/purposes they agree to give their data/samples?

Informed Consent Considerations:

- The future use of data/specimens, with checkboxes for subjects to agree or disagree to specific uses of their data/specimens for specific research purposes (when applicable).
- If and how subjects will be informed of any incidental findings or other new information related to the research. Whether subjects may be re-contacted for future research studies.
- Procedures for protecting the privacy of subjects and maintaining the confidentiality of the data.
- Whether or not subjects may withdraw their data and/or specimens, and if so, how they would relay this request to the investigator(s).
- If human biological specimens are involved, language that states that the research may result in new discoveries and that the donor-subjects will not retain any property rights to their materials.