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Health Research Ethics Committee (HREC)

NEW DATABASE/BIOBANK APPLICATION: Guidance and instructions for researchers

Instructions

New Database/Biobank application

The Health Research Ethics Committee (HREC) uses an electronic ethics review management system, *Infonetica*©, to manage the application and review process.

» This is a new system and we recommend that you consult the **APPLICANT MANUAL** for guidance

» To access the electronic submission platform for your HREC application, please click here: **APPLY HERE**

» Once the login is Successful, select the "Create Project'' Tile on the second row on the left hand side under the actions drop down list

- Should log in be unsuccessful please verify your Sun ID account with your home department and try again at a later stage.

» After the "create project" tile has been clicked a "create project'' box should appear whereby you should enter the full project title and then select the appropriate form; in this case it's the **HREC Biobank Application Form and press the create button**

» Once this has been done, Under the **HREC Biobank Application Form** you can now start the application by clicking on Page 1 in line with Section 1 marked '"Database, Registry or Repository".

» You can now start with your application

- For Further information consult the Applicant Manual.

What needs to be submitted?

1. Please submit an online application through *Infonetica*©
2. Please prepare the following supporting documentation which you will be asked to upload during the electronic application process.

Database or Biobank
1. Standard Operating procedure (SOP) document for the database/biobank, including a. Background and rationale for creating the database/biobank, including the purpose of the database/biobank and the topic of future database/biobank-based studies b. Participant (donor) inclusion & exclusion criteria c. Participant (donor) recruitment d. Data and sample collection e. Data and sample storage, including de-identification / anonymization procedures f. Access to data/samples g. Ethical considerations including informed consent, risks and benefits, participant compensation etc.
2. Participant Information and Consent Form (ICF)
3. **Two-page** CV for each investigator
4. Signed Investigator Declaration for each investigator
5. Budget (and financial contract, if external funding)
6. Flow chart depicting the process of data/biological material accrual and release.

7.	Template application form for access to data/biological material.
8.	Recruitment materials (adverts, flyers, posters)
9.	Data collection tools (e.g. survey, questionnaire)
10.	For studies that intend to send/receive data or samples to/from another location, a Data/Material Transfer Agreement (DTA/MTA) Term Sheet.
11.	Withdrawal form: for the participant to request withdrawal of their data or sample/accompanying data from the database/biobank.

Post Submission Guidance

Responding to the HREC's feedback

- Address all points and queries in a cover letter, using examples, references and data where necessary.
- Copy or restate the question or concern raised by HREC and then provide a detailed and thoughtful response. Incomplete responses are likely to trigger a repeat query from the reviewer.
- If a reviewer's feedback is unclear or ambiguous, contact the HREC staff and request clarification. If you disagree with a comment or recommended change, provide your rationale.
- If the response requires a change in database/biobank procedures or design, revise the relevant documentation e.g. Biobank SOP, protocol, recruitment materials and information sheets/ consent forms accordingly.
- If your response requires revisions to documents, submit copies with changes highlighted in track changes so the reviewer can immediately determine where and what changes have been made.
- Proofread the final versions for grammatical, typographical and formatting errors.

Annual Progress Reports (Continuing Review of Ongoing Research)

International and national regulatory and ethical requirements require the HREC to review active research at least annually. The PI is responsible for submitting an annual progress report to the HREC in a timely manner before the approval period for the study expires. The HREC has the authority to suspend or terminate research which does not comply with annual reporting requirements.

Active Protocols

All changes or amendments to the biobank/database, including for example information/consent documents, advertisements, addition of investigators must have HREC approval prior to implementation except where necessary to eliminate immediate risk of harm to enrolled participants.