CIRB Update: Removal of Categories 7 to 10 in the Exemption Application Form

(A) Summary of Changes

CIRB Exemption Application Form, categories 7 to 10 were adopted based on the recommendation in the Singapore BAC's Guidelines for IRBs on *Research Involving Human Subjects* (November 2004). Exemption categories are not specified in the Human Biomedical Research Act (HBRA).

In streamlining our review processes with the HBRA's requirements, the following exemption categories will no longer be applicable with immediate effect.

Category 7 – Reporting of Individual Patients' Clinical Results
Category 8 – Research using Unidentifiable Data
Category 9 – Commercially Available Cell Lines, Anonymous DNAs, RNA and Fixed Tissues
Category 10 – Development of Diagnostic Tests

(B) Removal of Exemption Categories 7-10

Category 7 – Reporting of Individual Patients' Clinical Results

Case report of one to two patients does not meet the definition of research as it does not involve "systematic analysis/ investigation". Studies involving three or more patients (case series) will require CIRB review.

Note: For case reports publication, it must be prepared in accordance to institutional rules and regulations.

Category 8 - Research using Unidentifiable Data

Use of (i) previously collected anonymous data; or (ii) existing dataset that has been stripped of all identifying information and there is no way that it could be linked back to the individuals from whom it was originally collected (through a key to coding system or by any other means), does not constitute human biomedical research as there is no interaction with any individual and no individually-identifiable information is used.

Category 9 - Commercially Available Cell Lines, Anonymous DNAs, RNAs and Fixed Tissues

Established commercially available cell lines or commercially available anonymous DNAs, RNAs and fixed tissues are not individually identifiable. Research studies involving the use of established commercially available cell lines or commercially available anonymous DNAs, RNAs and fixed tissues do not meet the definition of human biological research and would not require IRB approval/review.

The US-Office for Human Research Protection's guidelines state that "…in vitro research and research in animals using already derived and established human cell lines, from which the identity of the donor(s) cannot readily be ascertained by the investigator, are not considered human subject research and are not governed by the HHS or FDA human subject protection regulations appearing at 45 CFR Part 46 and 21 CFR Parts 50 and 56. IRB review is not required for such research."

However, IRB application should be submitted for the following research studies:

(1) Prohibited and Restricted human biomedical research as described in the Third and Fourth Schedule of the HBRA (Refer to Appendix 1)
(2) Creation of a tissue bank or conduct of any tissue banking activities with human biological material
(3) Use of individually-identifiable human biological material

Category 10 – Development of Diagnostic Tests

The use of existing anonymised* human biological materials for test validation purposes will not require CIRB review. These materials are in existence and there is no prospective collection of human biological materials.

***Anonymised** means that the collected samples/data have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples/data to the sources. This process does not preclude linkage with existing clinical, pathological, and demographic information before subject identifiers are removed (Reference: Sheet 14: NIH Requirements for the Research Use of Stored Specimens and Data (Jun 12, 2006)).*

(D) Management of Studies or Applications with Exemption Categories 7-10

Approved Exempted Studies

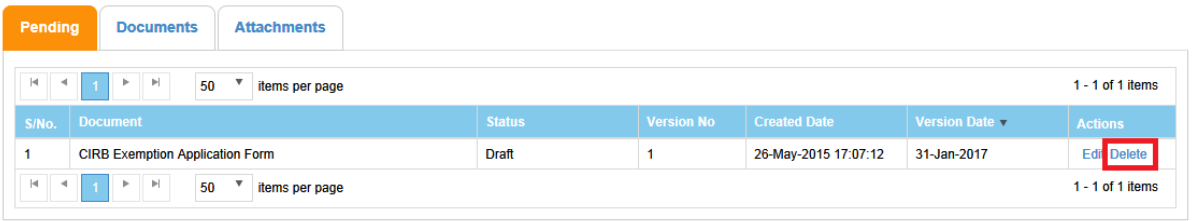
For studies approved with exemption categories 7-10, subsequent amendments to such approved studies is not necessary as IRB review is no longer required.

Submitted Applications pending CIRB review

CIRB will cease to accept any exemption application with categories 7-10 with immediate effect. For applications that have already been submitted, CIRB will review the applications. CIRB may also contact the Principal Investigator of the submitted application, if needed.

Applications in Draft

For applications in draft stage, the Principal Investigator of the application can delete the draft in the Study Workspace. Kindly note that draft application at the stage of Pending PI Declaration, RDO Check or DR/IR endorsement, the delete button would not be available.



If you have any questions, please contact CIRB at irb@singhealth.com.sg.

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Defining Tomorrow's Medicine

APPENDIX 1

HUMAN BIOMEDICAL RESEARCH ACT

THIRD SCHEDULE: PROHIBITED HUMAN BIOMEDICAL RESEARCH

1. Human biomedical research involving the development of human-animal combination embryos referred to in paragraph 2(a)(i) or (iii) of the Fourth Schedule beyond 14 days or the appearance of the primitive streak, whichever is the earlier.
2. Human biomedical research involving the implantation of any human-animal combination embryo into the uterus of an animal or a human.
3. Human biomedical research involving the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of living great apes whether prenatal or postnatal.
4. Human biomedical research involving the breeding of animals which have had any kind of pluripotent stem cells (including induced pluripotent stem cells) introduced into them.

FOURTH SCHEDULE: RESTRICTED HUMAN BIOMEDICAL RESEARCH

1. Human biomedical research involving human eggs or human embryos.
2. Human biomedical research involving —
   (a) the following types of human-animal combination embryos:
      (i) cytoplasmic hybrid embryos;
      (ii) human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells);
      (iii) human-animal combination embryos created in-vitro by using —
         (A) human gametes and animal gametes; or
         (B) one human pronucleus and one animal pronucleus;
   (b) the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo;
   (c) the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal;
   (d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal; or
   (e) any entity created as a result of any process referred to in sub-paragraphs (b), (c) and (d).
3. Nothing in this Schedule is to be construed to permit any human biomedical research that is prohibited under the Third Schedule.