Research Administration Workflow
(online approvals)

Go-Live currently scheduled for June 16th, 2019

Training – see website for details

Questions? Contact your research facilitator or visit uab.ca/RSO
Research Ethics

What’s new?

Kim Kordov – Association Director, Research Ethics Office
Objectives

• Learning Objective #1 - Gain a deeper understanding of ethics review process and requirements.

• Learning Objective #2 - Understand high level changes to the environment related to research ethics review.
What Needs Ethics Review

Human Participant Research (TCPS2):
The following requires ethics review and approval BEFORE the research commences:

- Research involving living human participants
- Research involving human biological materials (whether derived from living or identifiable deceased individuals)

Where - “research” defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Animal Research (CCAC)

All research, teaching and testing involving animals

- Cephalopod or higher (vertebrates)
What Needs Review?

All human participant research and animal research, teaching and testing under University jurisdiction (conducted by Faculty, staff or students) requires approval whether:

- it is funded or is non-funded;
- it is conducted in Canada or abroad;
- it is conducted on University property or off;
- it is conducted in a laboratory or in the field;
- it is conducted to acquire basic or applied knowledge;
- the research is a pilot study or a fully developed project

WHEN IN DOUBT CHECK IT OUT!!
What May Be Exempt

Human Participant Research

• Research that relies exclusively on publically available information does not require REB review:
  • When that information is legally accessible to the public (i.e. Canada census data)
  • When that information is publicly accessible and there is no reasonable expectation of privacy (i.e. Internet accessible information)
• Research that involves the observation of people in a public place where they have no reasonable expectation of privacy
• Research that relies exclusively on secondary use of **anonymous** information or anonymous biological materials so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.
What May Be Exempt

Animal Research

- Category A invasiveness
  - Observation of live animals in their environment with NO modification to environment or behavior
- Invertebrates
- Live isolates – parasites collected from live animals, zebrafish embryos, chicken embryos (up to 14 days post fertilization)
- Animal derived tissues/cadavers (where the tissue already exists under an AUP)
- Other non-research/teaching involving animals on campus

- Complete Exception to ACUC Review Form
Does this need review?

- Using human biological specimens obtained commercially?
- Using non-identifiable human data from a large US database that is available to University researchers with a data sharing agreement in place?
- Using Twitter feeds to answer your research question?
- Using animal tissues that are harvested for you by a colleague at another University (they have ethics approval)?
- U of A Researcher conducting a human participant research study in Poland but they are getting ethics approval there?
- Researcher going into the field and setting up bait stations to draw animals to an area observe animal behavior?
- Research involving fruit flies to learn about neurological behavior
When?

- Ethics approval has to be obtained **BEFORE** the research begins and, in the case of funded research, **BEFORE** funds are released.
- Approval has to be **maintained** (renewed annually) for the duration of the research activity.
- Changes to the approved research must be approved by the REB or ACUC before they are implemented.
Release of Funds

• Per University of Alberta policy:
  • researchers must obtain appropriate ethics approval and certifications – human, animal, biohazards and stem cells – before they start their research
  • AND RSO must verify that these certifications and approvals are in place before allowing access to research funds.

• Release of Funds – allow researcher to access funds if the first months or years of a grant DO NOT INVOLVE human participant or animal research

  MAXIMUM DURATION OF A RELEASE OF FUNDS AGREEMENT IS ONE YEAR. It is the responsibility of the researcher to either renew the agreement or obtain ethics approval prior to the expiry date.
Applicable Policy – Human Research

UAPPOL – Human Research Ethics Policy
https://policiesonline.ualberta.ca/PoliciesProcedures/Pages/DispPol.aspx?PID=48


UAPPOL – University of Alberta Research and Scholarship Integrity Policy
https://policiesonline.ualberta.ca/PoliciesProcedures/Pages/DispPol.aspx?PID=70

Various other regulations depending on type of research (biomedical/health) and funding (i.e., US NIH), *Health Information Act*
Applicable Policy – Animal Research

UAPPOL – Animal Ethics Policy

Canadian Council on Animal Care in Science (CCAC)
www.ccac.ca
Applicable Policy – What’s New

- Updates to TCPS2 – expected in June 2019
- Updated US Common Rule – January 2019
  - applies to research funded by US Federal Funding (Department of Human & Health Services)
  - Revisions to:
    - Categories of Exemption
    - Requirement for Continuing Review
    - Broad Consent - a new type of informed consent provided under the revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens
    - Informed Consent - the consent form, and the consent process, should provide subjects with the information needed to make an informed decision about whether to participate.
    - Posting consent forms – clinicaltrials.gov

Some does not apply to Canadian research because TCPS2 rule do not allow.
Applicable Policy – What’s New

UAPPOL – Animal Ethics Policy
- completely updated April 2019
- Non-compliance Procedure – guidance for maintaining compliance and definition of non-compliance.

Canadian Council on Animal Care in Science (CCAC)
- Updates to Pedagogical Merit Review process
- Updates to requirements for review of research collaborations
Cannibas Research

• Legalization – October 2018

• Research
  • Health Canada Requirements - Drug
  • Institutional License required – in progress
  • Effectively – cannot use in research until this is finalized

• Other Issues:
  • Source of funding? (ie. public perception, Tobacco sponsorship not allow – is Cannibas the same)
  • Conflict of Interest?
REMO – Research Ethics Management Online

https://remo.ualberta.ca OR

REMO - Apply for Ethics

Link from U of A and Research Ethics Office websites

What’s New”

• Major upgrade 2019
  • updated look and feel
  • Ease in navigation – dashboard
  • Updated help resources on REO website
HELP!

Help & Video Tutorials for Using the REMO System

Video tutorials or help documents for using the REMO system are available below, separated for animal use applicants and human research applicants.

** Please note the new URL for this page and update your bookmark **

** Due to the system update in Feb 2019, videos and help documents are currently being updated. **

Animal Use Application

- Navigating the Online System - an overview of your personal homepage in REMO and demonstrates how to view your studies
- How to Add or Change Personnel on an AUP
- How to Add or Change Funding on an AUP
- Renewals - How to create and submit a renewal
- How to find and save your Approval Letters
- How to start a new animal use protocol

Human Research Application

- Navigating the Online System - An overview of using REMO and finding your studies
- Request an additional role - How to request an additional role for your REMO profile (if someone cannot find your name in a dropdown box to add you to their study)
- Change Personnel - How to ADD or DELETE personnel on an approved REMO application
- Change Funding - How to ADD or DELETE a funding source from an approved REMO application
- Reviewer Notes - How to find and respond to the REB's request for revisions by accessing the "reviewer notes"
- Students as PI - How to edit your REMO profile if you are student PI
- Renewals - How to create and submit a renewal application
- Approval Letters - How to view/find and save an approval letter
- Copy an Existing Study - How to copy an existing REMO application to use as the starting point for a new application
- Documentation - How to ADD, EDIT and DELETE documents from Section 7.1 in the REMO application
- Change Document Title - How to change the title of a document in REMO without uploading a new document
- Amendments - How to create and submit an amendment application
- How to Print Approval Letters - How to print your study approval letter in IE, Chrome, Firefox (pdf)
Planned REMO changes

• Animal Form Revisions – Renewal/Amendments
• Reportable Events Module (June 2019)
• System name change – Uarise
• Animal Form Revision – Full AUP
• REMO/Grants integration
• REMO/IRISS Exchange
Be The Cure
Stay Up To Date

- REONews
- Updates to policy
- Guidance
- Process changes
- Form updates
## REO Resources

Research Ethics Office
Website – [www.uab.ca/reo](http://www.uab.ca/reo) for resources and contact information & templates

**VIDEO Tutorials:** [https://www.ualberta.ca/research/support/ethics-office/education-training-user-support/remo-support/help](https://www.ualberta.ca/research/support/ethics-office/education-training-user-support/remo-support/help)

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<thead>
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Research & Ethics Management Online (REMO) System

https://remo.ualberta.ca
Online Evaluation Form

• We appreciate your help in evaluating this presentation!
• The RAD evaluation form is accessible online. Click here or click on the blue checkmark below (right-click the hyperlink(s) and click Open Hyperlink to activate).