Comparative Oncology Clinical Trials: Ethics, Oversight and Conduct.

Workshop Best Practice Recommendations

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Workshop on Conduct, Oversight and Ethics of Clinical Trials in Comparative Oncology

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Principles

Clinical Trials must preserve patient well-being and provide best supportive care and the relief of pain and other distressing symptoms.

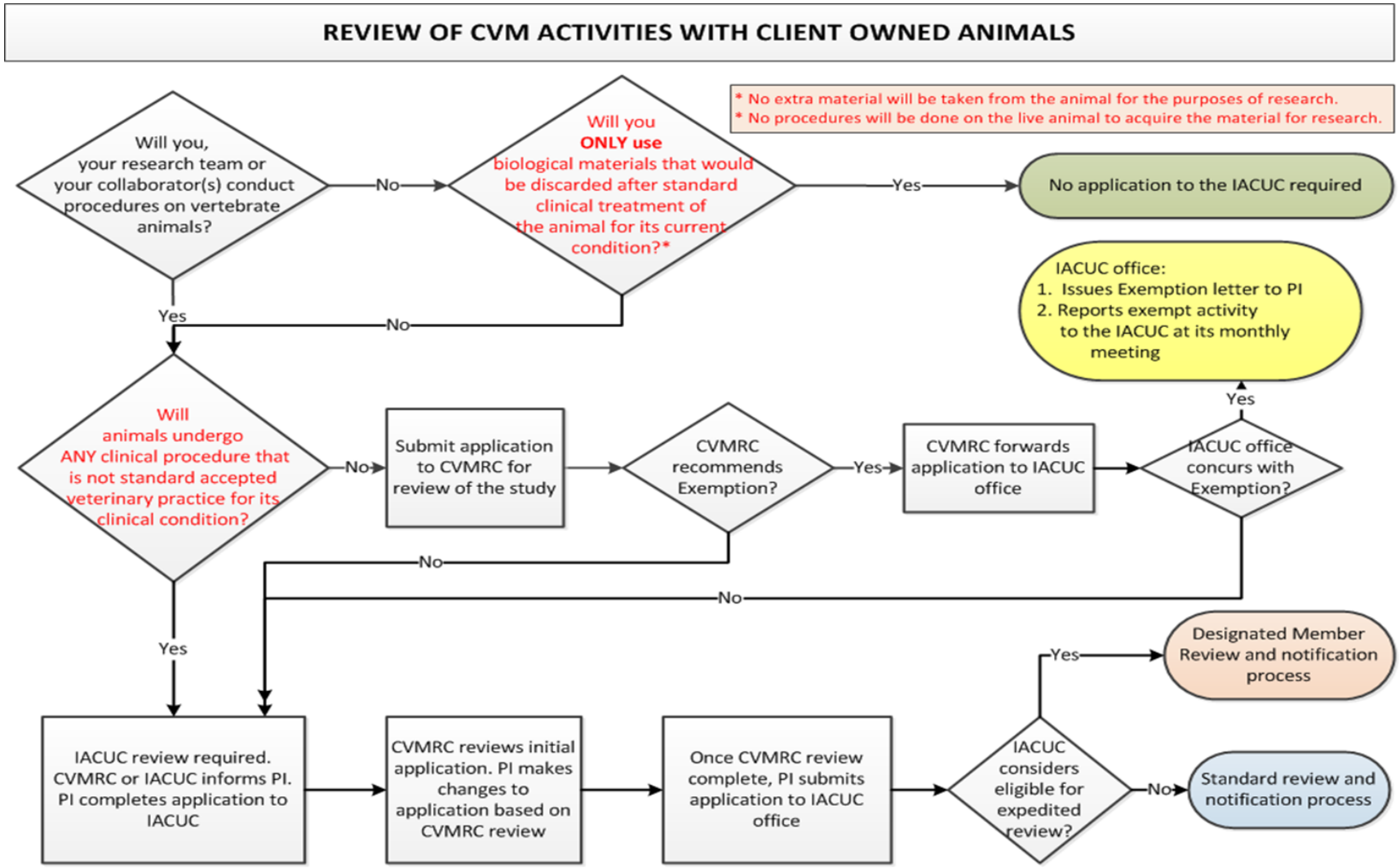
All clinical trials should be peer reviewed for scientific and therapeutic merit, feasibility, sound design and absence of redundancy.

The consent process must be honest, thorough and well communicated and the pet owner must have adequate time to consider participation without real or perceived coercion or conflict of interest.

Accountability and oversight of research conduct by all those involved must be maintained. https://ori.hhs.gov/sites/default/files/rcrintro.pdf

Continued improvement of and education in clinical trial conduct and oversight is critical to both animal health and appropriate translation of such data to human health.

Clinical Trial Approval Process



Baneux, et al. ILAR Journal 2014, 55:200-209

Informed Consent *Process*

Ethical assurance of companion animal patient welfare and owner comprehension of trial goals and compliance.

Harmonize with IC Process for Humans where possible.

IC Form Compliance: http://www.hhs.gov/ohrp/policy/consentckls.html

Continual evolution of process:

- FDA Guidance, http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf
- PRIM&R, www.Primr.org

2013 NCI Template – http://ctep.cancer.gov/protocolDevelopment/informed_consent.htm

Informed Consent Process – Workshop Recommendations.

Consenting process management:

- ✓Consenting Team
- ✓Clarify study purpose
- ✓Thorough description of study design and interventions
- ✓Funding source & conflict of interest disclosures
- ✓Compensation and vulnerability
- ✓Advocacy and client support
- ✓Comprehension and Retention

Post-Approval Monitoring: Workshop Recommendations

- ✓ Education and Training Programs
- ✓ Implementation Resources
- ✓ Adapt NCTN Audit Guidelines:

  Eligibility, IC Process, Protocol Compliance, Adverse Event Reporting.

  http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf

- ✓ Confidential Contact Process

Reporting and Publication: Workshop Recommendations

Trials Registry

Data management systems

Publication

- CONSORT Guidelines
- Improved publication policy:
  - *McGrath, et al. BJP 2015, 172:2427-2432.*
  - Increased accountability of animal use, open access to all primary data including negative studies.

Reduce, Replace, Refine…

Clinical Trial Process Improvement

- Adopt ‘Clinical Trial Best Practice Recommendations’
  - How?
  - Regular Review and Revision
- Encourage Research on Trial Conduct Process
  - Increased comprehension, enrollment and retention
  - Role of patient/owner reported data
- Provide education to all stakeholders regarding the clinical research process - professional training programs.
- Promote awareness and value of comparative clinical research

Adopting a ‘Best Practice’ approach to clinical research by continually improving scientific and ethical conduct of trials and providing extraordinary protection for animal patients and their owners will create trust leading to increased participation and better integration of comparative medical research with shared health benefits for all members of the family.