Scientific Working Group for Forensic Toxicology (SWGTOX)  
Committee

1. Introduction

1.1. The broad objective of the Research, Development, Testing, and Evaluation (RDTE) Committee of Scientific Working Group for Forensic Toxicology (SWGTOX) is to develop recommendations for research, development, testing and evaluation to support the underlying science on which the practice of forensic toxicology is based.

1.2. The impact of novel and systematic forensic toxicology research will improve public health and safety, inform public policy, support the criminal justice system, and generate greater understanding of the adverse effects of drugs and toxicants with medicolegal or other punitive consequences.

1.3. Evidence-based knowledge of the mechanisms, risks, and dangers of drugs and toxicants are derived from academic, clinical and forensic laboratory innovations throughout the world, yielding scholarly publications advancing forensic toxicology interpretation, methodology, and technology.

1.4. Forensic toxicology researchers and practitioners continue to make seminal contributions to the scientific foundation of the field, yet significant critical gaps still exist. Research in forensic toxicology spans from bench-level laboratory methodologies to basic and clinical science investigations.

1.5. This document describes the areas of research focus, priorities and practices in forensic toxicology, as well as, provides recommendations to advance the science of forensic toxicology.

1.6. The intended audience for this document includes investigators, laboratory managers, policymakers, governing bodies, and others who would benefit from a better understanding of RDTE efforts in forensic toxicology.

2. Definitions

2.1. Research - A hypothesis-driven systematic investigation of forensic toxicology, including the generation and analysis of data, that advances the field and scientific knowledge base. Categories include basic, translational clinical, epidemiological, applied, and organized review and analysis of existing literature-based data.
2.2. Development - Improvement and enhancement of forensic toxicology methodology prior to testing, evaluation and implementation.

2.3. Testing - A systematic investigation of forensic toxicology methodology, including data generation advancing scientific reliability.

2.4. Evaluation - A systematic investigation of forensic toxicology methodology, including data analysis and interpretation advancing scientific validity.

2.5. Validity - The extent to which a conclusion, inference or proposition is accurate.

2.6. Analysis - The measurement of analyte and/or evaluation of data.

3. Focus of Forensic Toxicology Research

3.1. Characterization of Toxicants

Research studies elucidate chemical structure, mechanisms of action, pharmacodynamic effects (e.g., cognitive, psychomotor, physiological, subjective) and pharmacokinetics. This research includes analytical method development.

3.2. Factors Affecting Interpretation of Forensic Toxicology Data

Research studies address biological, chemical, analytical, and other relevant factors that influence interpretation of forensic toxicology data. Research approaches include laboratory, field, animal, epidemiological, and clinical studies of these factors to further understand their relevance to forensic toxicology.

3.3. Novel Technology for Forensic Toxicology Analysis

Applications of novel approaches and matrices, and innovative approaches to forensic toxicological analyses provide a foundation for advancement of the discipline.

3.4. Utilization of Existing Data and Knowledge

Enhance utilization of existing data and knowledge through data mining strategies, access to peer-reviewed literature, and database development to facilitate laboratory and informatics studies.
4. Priorities for Research in Forensic Toxicology

This list of priorities for research topics in Forensic Toxicology is not exhaustive; it will be reviewed and updated as necessary. Priorities are listed in alphabetical order and are not ranked.

4.1. Breath Alcohol
4.2. Building, Mining and Disseminating Forensic Toxicology Databases
4.3. Chemical Terrorism
4.4. Drug Interactions
4.5. Drug Metabolism and Parent-to-Metabolite Relationships
4.6. Environmental Toxicants (e.g., metals and non-metallic elements, plasticizers, pesticides, flora and fauna)
4.7. Emerging Drugs of Abuse
4.8. Herbal and Dietary Supplements
4.9. Matrices (e.g., alternative, decomposed, embalmed, non-preserved)
4.10. Nanotoxicology
4.11. Non-traditional Forensic Toxicology Analyses (e.g., endogenous and exogenous markers, siRNA, peptides, proteins)
4.12. Novel Analytical Techniques
4.13. Pharmacodynamics and Pharmacokinetics (e.g., tolerance, relationships)
4.14. Pharmacogenetics and Pharmacogenomics
4.15. Population-based Toxicology (e.g., sex, race, disease states, pregnancy, elderly, pediatric, toxic concentration ranges)
4.16. Postmortem Distribution and Redistribution of Drugs and Metabolites

5. Research Practices in Forensic Toxicology

Forensic research draws upon many scientific disciplines and is hypothesis-driven or exploratory in nature. Effective use of experimental design, controls, valid methods of analysis, statistical and interpretive evaluation of results are essential components for successful research, preferably leading to peer-reviewed publication. Experimental design will be dependent on the specific research objective and is subject to appropriate oversight.
5.1. Areas of Practice

Research is conducted to elucidate and quantify physiological and behavioral effects, and the relationship between concentrations of drugs, other toxicants, their metabolites, or other biomarkers of exposure, with respect to:

5.1.1. Human Performance Toxicology (e.g., drug facilitated crimes, driving under the influence of alcohol or drugs)

5.1.2. Postmortem Forensic Toxicology

5.1.3. Non-regulated employment drug testing

5.1.4. Court ordered toxicology (e.g., probation and parole, drug courts, child services)

5.1.5. General forensic toxicology - other toxicology performed for legal purpose in a variety of biological specimens (e.g. non-lethal poisonings or intoxications).

5.2. Oversight of Forensic Toxicology Research

Forensic toxicology research may require institutional, organizational, or regulatory oversight. Investigators should consider the relevance of the following to their research and incorporate these procedures during the early stages of the research:

5.2.1. Institutional Review Board (IRB) - The ethical use of human subjects or their biological specimens must be reviewed and approved by an IRB prior to initiation of research. This review includes evaluation of scientific merit, experimental design, risk-benefit assessment, justification of subject inclusion, informed consent, and safety.

5.2.2. Health Insurance Portability and Accountability Act (HIPAA) - The privacy of individually identifiable health information must be protected.

5.2.3. Institutional Animal Care and Use Committee (IACUC) - Protocols for animal experimentation must be reviewed and approved by the IACUC. This review includes elements such as evaluation of scientific merit, experimental design, justification of species and number of animals, and safety.

5.2.4. Local and private IRB and IACUC organizations are available to investigators.
5.3. Selected Resources for Responsible Research

The standards and legal requirements for responsible research are defined by multiple government and private agencies. These resources are available to provide further clarification regarding the responsible and ethical conduct of research. All researchers and practitioners must be knowledgeable of institutional and local, state and federal requirements.

Note: All hyperlinks accessed on 11/15/2011

5.3.1. Responsibilities of the Research Investigator

http://answers.hhs.gov/ohrp/categories/1567
http://healthcare.partners.org/phsirb/PI_Responsibilities.htm

5.3.2. Special Obligations in Human Subject Research

http://www.hhs.gov/ohrp/international/intlcompilation
http://ohsr.od.nih.gov/
http://bioethics.od.nih.gov/IRB.html

5.3.3. Laboratory Animals in Research

http://grants.nih.gov/grants/policy/air/
http://oacu.od.nih.gov/
http://science.education.nih.gov/animalresearchfs06.pdf
http://bioethics.od.nih.gov/animals.html
http://www.nimh.nih.gov/research-funding/grants/animals.pdf
http://grants.nih.gov/grants/olaw/olaw.htm

5.3.4. Research Involving DNA and Stem Cells

5.3.5. Data Use, Integrity, Ownership, Storage, and Retention

http://ori.hhs.gov/education/products/clinicaltools/data.pdf

5.3.6. Authorship and Publication

http://www.icmje.org/ethical_1author.html

5.3.7. Conflict of Interest

http://www.icmje.org/ethical_4conflicts.html
http://www.nih.gov/about/ethics_COI.htm
http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals

5.3.8. Reporting to Funding Agency and/or Proprietary Research

Refer to specific funding agency requirements

5.3.9. Ethics and Obligations to Report Interference, Misconduct, and Errors

http://www.wame.org/resources/ethics-resources/publication-ethics-policies-for-medical-journals
http://www.elsevier.com/wps/find/intro.cws_home/publishing

5.3.10. Intellectual Property

http://grant.nih.gov/grants/intell-property.htm
http://www.ott.nih.gov/about.nih/IPM-Resource-Data-Bank-International.doc
6. **Recommendations to Advance the Science of Forensic Toxicology**

6.1 Perform research to improve the quality, timeliness and practice of forensic toxicology, including interpretation of laboratory data.

6.2 Assure the availability of drug, toxicant, and metabolite reference materials and internal standards (e.g., native and stable isotope labeled compounds).

6.3 Develop a research assistance program to promote publication of forensic toxicology data generated by the practitioner community.

6.4 Develop and maintain on-line, curator-managed databases on specific forensic toxicology topics from multiple investigators or laboratories for interpretation (e.g., spectral libraries, case specific, special populations, alternative matrices, drug interactions).

6.5 Develop curricula, and other training opportunities to promote professional growth (e.g., technical writing, research design and ethics).

6.6 Develop mentoring, award and incentive programs for forensic toxicologists to perform and publish research.

6.7 Advocate diverse funding opportunities for research in forensic toxicology.

6.8 Encourage laboratory management to include research as part of the mission statement.

6.9 Participate in translational research initiatives including “from laboratory to courtroom”.