

Randall E. McClelland, Ph.D

SciKon Innovation, Inc.
PO Box 9100
Chapel Hill, NC 27515

email: randy@scikoninnovation.com
d: (919) 354 - 1083

INTERDISCIPLINARY: Biotechnology, Tissue Engineering, Modeling and Data Predictions and Data Mining, Biomedical Engineer, Biology/Stem Cell, Imaging, R&D Pharmaceutical, Cell-Biomaterial Responses, Bioenvironmental Health Engineering (EPA), Medical, Patient Healthcare (military and civilian).

OBJECTIVE: Informational

REFERENCE: Background

SKILL SETS: My interdisciplinary backgrounds encompass arrays of activities to include advanced medical and biomedical tissue engineering, cell therapy transplantation, pharmacology and toxicology data-mining, military bioenvironmental health, modeling with data acquisition and prediction of tissue-health activities, direct patient care, and translational medicine. My business expertise integrates entrepreneur skills in biotechnology, directing R&D of pharmaceutical biotech companies, supervisor of health-care departments, director of military bioenvironmental departments (EPA & Public Health), and oversight of interdisciplinary health-research collaborations.

DIRECT EXPERIENCE

- Entrepreneur, Biotechnology Co.
- Biomedical Project Management
- Clinical Diagnostics
- Director of Bioreactor Group
- Biotech Mergers and Acquisitions
- Business developments
- NIH / SBIR Grants
- Phase I, II, Fast track
- University Collaborations: Engineers/Biologists/Physicians
- Industry Collaborations: Large Pharmaceuticals and Startups.
- Contract Negotiations
- Research & Development Manager / Leader / SOPs
- CRO development / implement
- Technology Transfer
- Intellectual Property
- Liaison between Scientific PI
- Conference presentations / Lectures
- Facilities Management
- Team Leader, Scientific

DIRECT EXPERIENCE

- Lead Company Weekly Meetings
- Educational Team Member
- People Management Courses
- Healthcare Private Hospital Supervisor
- Military Bioenvironmental Engineer Supervisor
- Lead Inspection Teams for Healthcare Facilities
- Lead Credentials Teams for Physician Monitoring
- Motivation / Team Player awards (*mult. years), peer/supv. recognition.
- Manger of Radiology Department
- Lead External Collaborative Discussions
- Subordinate Reviews
- Direct Patient Care, ER, OR, Diagnostic
- Liaison between healthcare workers
- In house teaching, CME, OJT
- Extensive DoD Background
- Focus on new patient care technologies
- Biotech company asset transfers

FORMAL EDUCATION

- Post doc: Cell & Molecular Biology 3yr
- Post doc: Small animal imaging 2yr.
- Heat Transfer and Fluid Flow
- Bioengineering / Biotechnology
- Convective Heat Transfer
- Electricity I / II
- Advanced Engineering Math I
- Advanced Engineering Math II
- Special Topics in Cell Biology
- Tissue Engineering
- Topics in Cell and Molecular Physiology
- System Physiology
- Surfaces & Interfaces in Mat.Chemistry
- Animal Surgery
- Finite Element Analysis
- Mathematical Modeling of Eng.Systems
- Engineering Metrology
- Biophysics
- Behavior of Materials
- Dispersive flows supporting 3D tissues
- Engineering undergrad courses

SUMMARY OF QUALIFICATIONS

- Entrepreneur for Tissue-Health and Translational Engineering: Facility search, contract negotiations, leadership activities. Oversight for company mergers, sales, marketing, product distributions, facility costs, and equipment. Contract research outcomes, product developments and derived goods, evolving SBIR grant portfolios, and networking. Patent reviews and submissions. Academic research collaborations and contracts.

- Industry project leadership (Strategic and Tactical). Regional Leader, Biotechnology Company: Assumed duties to realign product developments and market potentials. Oversight for decreased overhead cost, sales, improved marketing, evolved product distributions, and equipment. Developing revenues via CRO outcomes, new product developments, new goods derived from stocked assets, evolved SBIR portfolios, and networking. Rebuilding company structures.

Research impacts the biomedical engineering field of tissue-health engineering, and is focused on cellular responses to environmental changes - both experimentally and computationally. Experimentally, tissues are analyzed within *in vitro* bioreactors and *in vivo* small animal models via morphology, functional, and image assays. By modifying microenvironments (e.g. chemical toxins, material properties, extracellular matrix variances, nutrient concentration distributions, cell specificity labeling, etc.), the efficacy of tissue support systems can be designed, analyzed, and improved. Concurrently, cellular microenvironments are computationally analyzed using fluid flow software packages, mathematical solvers, and predictive modeling to investigate nutrient flux characteristics prior to design prototyping. In this way, computational analysis help to decrease experimental costs, allows for mathematically derived “novel modifications”, and improves the success of marketable biodesigns.

- Industry project leadership with human tissue science (Tactical and Operational). Directing biomedical engineering projects including: (1) Bioreactor 3D device developments for material science chemistry, nutrient flow patterns, cell function and metabolism, human tissue processing, QC, product distribution, and culture quality improvements. (2) Collaborations with large pharmaceuticals for drug toxicity analysis including R&D assignments, data interpretation, establishing timelines, product alpha and beta trials, and decision trees. (3) Evolving proliferation and differentiation protocols for human liver stem cells (fetal, neonate, adult). (4) Successful cryopreservation of primary human cells as “off-the-shelf” tissue products (e.g. cells on demand). Managed internal and external personnel. Consistently projected and operated within budgets.

Creating 3D human tissue constructs to better support pharmaceutical/toxicological labs for drug developments. Focus is on several items to include:

- Whole organ human tissue processing to retrieve better quality, higher quantities, and functionally distinct cellular components. This includes large scale perfusions, sterility, and the cell sourcing applications.
- Cell sourcing is from nontransplantable donor tissues. Adequate sourcing is critical to final product success. Sourcing variations include warm/cold ischemia, -intra and -extra cellular fat content, tissue age, and history of toxic assaults.
- Purification of human cell stock solutions is complicated by excess amounts of red blood cells, debris during organ retrieval and shipping, apoptosis, necrosis, fat content, and extended transport times. Each tissue is an experimental process with inherent variability. Purification is accomplished by gradient techniques, membrane specificity applications, and live/dead segregations.
- New matrix applications for 2D and 3D cell support, proliferation, differentiation.
- Perfusion bioreactor developments. Convection, Diffusion, and Dispersion of nutrients. New plug-n-play bioreactor designs using Solid Works designs. Inclusion of pneumatic pumps for recirculation of media nutrients.
- Customer relations include large/small pharmaceutical companies. University research labs. Collaborative efforts with biotech companies.
- New assays to predict cellular activities for high throughput and micro-scale tissue sources.
- Liver Stem Cell consultant for sister company doing Stem Cell Therapy clinical trials.
- Review of company IP to create new market applications based on human tissue products.
- Conference attendance for networking.

- IP creation and patent reviews.
 - Assist in European GMP cell processing by creating culture heat and gas flow designs, improving cell processing techniques, and developing perfusion media flows.
- Grants (translation health proposals). Over the last 3 years, submitted more than 20 health-related SBIRs as primary investigator. Other proposals include Co-PI and subcontractor relationships. Grants routinely involve pharmaceutical industry (small / large) and academic partners and require networking with biologists, engineers, applied sciences, chemists, pharmaceuticals, and clinicians. A few selected narratives are:
- “Complex Liver Modules for High Through-put Transomic Data Generation; Primary Embryonic and Adult *in vitro* Systems”. EPA studies are focused on enhanced predictive pathways, relating animal and human *in vitro* cell and tissue-based tools for toxicity testing, that are needed to enhance predictability of structure activity relationship, so ultimately chemical structural motifs can be used *in silico* to determine potential toxicity. The adage, “*Your in silico model is only as good as the biological data you are entering*”, reflects the roadblock that EPA Toxcast, virtual-Liver, and virtual-embryology programs are encountering. With advances in tissue engineering, specifically liver, the target organ for most toxicants, now permits high through-put determination of mechanisms of action using multiple “-omics” sciences as a robust read-out of sub-lethal and chronic toxicity.
 - “Human Tissue Responses to Chemical Toxins in a 3D Bioartificial Liver Device”, studies are aimed at predicting and investigating the underlying mechanisms involved in chemical-drug interactions and tissue toxicity characteristics for human tissue exposures. This 3D *in vitro* tissue platform will be utilized as an allogeneic toxicology tool for chemical toxin detection, specific tissue responsiveness, and ultimately improved health care protocols. The ability to directly investigate acute, chronic, and re-dosing of chemical toxins offers great potentials to more efficiently develop chemical analysis’ tools for improved life saving applications.
 - “A Scaleable Human Derived 3D Bioartificial Liver with Direct Cell Access”, studies are aimed to expand ADMETs human toxicology 3D MCB into a scaleable, compartmentalized, and indexed system to assist natural *in vivo* liver malfunctions. The compartmentalized system will be segregated into concurrent applications for *in vivo* organ support and *in vitro* cellular rejuvenations. Device indexing will rotate rejuvenated bioreactors inline with toxic media streams at timed intervals. Exhausted bioreactors will be synchronized into healthy media streams for cell rejuvenation. The research is expected to extend the effectiveness and duration of bioreactor applications by sequentially decreasing *in vivo* toxic media concentrations.
 - “Stem-to-Adult Cell Lineages in Humanized 3D Bioartificial Devices”, studies are aimed at the feasibility of 3-dimensional (3D) human liver tissue growth and function within a Multicoaxial Bioreactor. Characterizations, to include traditional media ELISA’s and NMR investigations, will categorize parenchymal liver cell populations from fetal, neonate, child, teen, young and older adults. This 3D *in vitro* tissue platform will ultimately be utilized as an allogeneic toxicology tool to assist in pharmaceutical drug developments.
 - “Microcarrier Conduits Supporting Hepatic Cell Therapy Engraftment Models”, studies are aimed at new scaffolds, novel forms of biodegradable microcarriers tailored for use by stem cells and by any cell type requiring polarity. The microcarrier scaffolds can be used both for culturing the cells and for transplanting them into hosts immediately after attachment or after culturing. They are especially ideal for cells from solid organs permitting transplantation of high numbers of cells under optimal seeding conditions into the organ or tissue. Since the cells are bound to matrix coatings on the microcarrier scaffolds, they are unable to migrate to undesired sites or to aggregate in ways leading to emboli formation. The technologies should lead to improved methods for cell transplantation particularly for cells from solid organs and will be some of the technologies central to regenerative medicine.
 - Drug discovery test models frequently are not predictive for their impact on human safety and efficacy, as indicated by the number of high profile pharmaceuticals have been pulled in the clinic or withdrawn after market after billions of dollars in development costs. We propose an innovative three-dimensional (3D) cell culture (bioreactor) system that will incorporate multiple human tissues such as intestinal, hepatic, neuronal, and cardiac cells to address the unmet need for predictive drug discovery tools. These tissues are involved in metabolizing drugs or are acutely sensitive to toxins. Several innovative technologies will result including 3D bioreactors and media formulations that promote survival and growth of a variety of human tissues, and high-resolution methodologies for the analysis of metabolites to quantify tissue-specific drug-related outcomes.

- “User-Friendly and Cell-Accessible Bioreactor: a simplified tool for 3D *in-vitro* cultures”, studies are aimed at streamlining complex interior bioreactor segments and simplifying interlinked exterior nutrient support components to convert a multi-unit device (>15 items) into a 2-component apparatus for consumer usability and simple culture reproducibility. These improvements, as desired by pharmaceutical companies struggling to meet drug development demands, will help to enhance 3D culture tools for predicting and studying the underlying mechanisms involved in cell-toxin interactions and drug re-dosing applications.
 - “Cells-on-Demand: Human Liver Progenitor Cells from Cryopreserved Adult Tissue Banks”, studies are aimed at 1.) Cell specificity purifications and 2.) High seeding efficiency of human liver progenitor cells derived from pre-existing cryopreserved banks of mature liver tissues. This is deemed necessary as it provides an alternative “off-the-shelf” resource of human liver progenitors for pharmaceutical companies that are struggling to meet demands of drug developments. When successful, cryopreserved progenitor cells with inherent expansion traits will be one option used as a reproducible and boundless cell resource.
 - “Hepatic differentiation of human umbilical cord matrix cells”, studies are directed at developing new technologies from differentiated human umbilical cord matrix cells. We will develop novel tissue based model systems which are physiologically relevant to mimic the *in vivo* environment of the human liver and to make these new technologies commercially available. The potential benefits of the proposed research is development of human liver models and tools that would positively impact all research and development areas that rely on alternative liver tissue sources.
 - “Systems Biology *in vitro* Approach” for drug discovery, studies are aimed at creating *in vitro* culture model systems comprised of human cells. System cultures will be linked together to better mimic natural *in vivo* tissue dynamics and improve predictive modeling for drug discovery. Inherent culture networks will contain several tissues that are either involved in metabolizing drugs or are acutely sensitive to toxins. Tissues from different organs will be aligned as series or parallel channels to induce system feedback signals, as analogously arranged in the natural body. Assembled *in vitro* cultures will allow secreted metabolites (and drug exposures) to circulate throughout media networks with subsequent and/or concurrent tissue exposures. During this SBIR R&D phase, the technical barriers of human intestine and liver cultures will be investigated with subsequent SBIR projects to include cardiac and neuronal tissues.
 - “Human Liver Cell Systems using Demographically Native Matrix”, studies are aimed to better recapitulate “mother nature’s natural organ design” and further establish humanized *in vitro* discovery models. The proposal will provide advancements in natural human liver matrix architectures; age and gender specific, to better support freshly isolated and cryopreserved human liver cells. Combined matrix-cell *in vitro* products will better mimic ECM-cell *in vivo* feedback signal designs. Matrix characterizations across tissue development timelines will provide ECM specific culture and growth factors.
 - “Fatty Liver Disease: AFLD and NALFD Mild, Moderate and Chronic Gene Signatures”, our studies categorize Gene Signatures that encompass fatty liver disease (FLD) human tissues. We expect to establish “Less Stringent” and “Stringent” Gene Lists using cell/tissue samples and linking medical history donor-tissue databases. This will not only help to generate predictive mild, moderate and chronic models of alcoholic (A) and non-alcoholic (NA) FLD outcomes, but also provide insight on the potential to clinically treat mild and moderate FLD patients, prior to chronic disease development.
- Eight years human cell sourcing and culturing experience within academic physiology labs and industry biotech companies. Strong biological foundation and a variety of transferable skills including cell growth, media formulations, extracellular matrix cues, biological feedback loops, cell specificity purifications, cell labeling methods, environmental cues, and toxicological responses for pharmaceutical drug developments. Engineering practices combined with biology skills provides unique understanding to relate living products (human tissues) with engineered applications and products. Collaborative opportunities and establish compliance, training, data collection, source documentation, validation, and personnel management.
- University project leadership and futuristic healthcare. Lead bioengineering projects incorporating multiple university campuses, labs, and industry partners. Several academic labs were completely funded by industry funds and required product development timelines. Expertise in human stem cell radiology-imaging at *small animal imaging facilities*. Provides a strong biophysics and biological foundation. Knowledge of radiology cell imaging areas include (1) microMRI using magnetic waves to track stem cell specifically labeled with

iron particles, *in vivo*. (2) microPET using radiation isotopes to track DNA modified stem cells, *in vivo*. (3) Phosphor imaging to confirm extracted *ex vivo* tissues are signal sources. (4) Computational image analysis to predict efficacies of stem cell therapy, including: (a) *in vivo* cell seeding, (b) cell migration, (c) cell-tissue integration, (d) cell viability, (e) cell growth, and (f) cell waning periods. Established cell therapy labeling techniques, both *in vitro* and *in vivo*, for short and long term tracking. Integrated radiology, biology, and engineering disciplines.

MRI in vivo Cell Tracking: MRI tracking of transplanted stem/progenitor cells was accomplished by exploiting EpCAM as a linker that attached magnetic nanoparticles to desired cell populations, followed by MRI. For *in vitro* controls, pre-established and quantified cell-spheroid-aggregates were created to identify three features: (1) correlate microscopy image details with ensuing MR image outputs, (2) determine maximum nanoparticle-cell concentrations based on viable cell culture timelines, and (3) determine MRI detection potentials derived from minimum nanoparticle distributions. Subsequently for *in vivo* studies, MRI combined with tissue histology confirmed transplanted labeled cells integrated within host tissues over short-term and long-term durations. For short-term MRI studies, a few days, human cells were labeled with nanoparticles using *in vitro* techniques, then transplanted into SCID/nod mice and MRI tracked. Restrictively, these signals quickly diminish over time as cells divide or break down the labels. For long-term *in vivo* MRI studies, greater than 2 weeks, non-labeled human progenitor cells were transplanted, allowed to integrate into host liver tissues, then contrast-nanoparticle labeled and MRI tracked. *In vivo* labeling occurred as EpCAM linked nanoparticles permeated through the animal's circulatory system and bound onto antibody-human-specific cell membranes. Beneficially, this *in situ* labeling technique permits repeat labeling, is not restricted by diminishing contrast signals, and provides the ability to monitor *in vivo* cell migrations and cell growths over time. These studies are efforts to develop experimental and clinical methods for optimizing transplantation of hepatic progenitors *in vivo* and being able to non-invasively monitor the cells after transplantation.

- Sixteen years of direct hospital patient care. Supervised a military radiology department. Managed the radiology sub-department of a private (civilian) level II trauma emergency room. Managed the radiology department of an Air National Guard medical division.
- A team-oriented professional who works well under pressure and is goal oriented. This has been acknowledged with several yearly and recurrent awards given by peers and management, see awards. Excellent written, verbal, and interpersonal communication skills. Comfortable speaking with medical affiliates, university academicians, industry leaders, and technical support staff.
- Management education and application: Ninth House Network management. The manager's role as coach. Managing negativity in the workplace. Interpersonal skills. Management problems of technical people in leadership roles. Handling the difficult well. Win-Win.

PROFESSIONAL EXPERIENCE

- **Nov. '08 – present:** Entrepreneur Tissue Engineering. Pharmaceutical and clinical *in vitro* and *in vivo* human cell applications. Human tissue Systems Biology. 3D culture developments. Diseased tissue investigations. SciKon Innovation, Inc. RTP, NC.
- **Mar. '84 – present:** United States Air Force (Active & Air National Guard).
 - **Mar '03 – present:** Major (Officer in Charge); Bioenvironmental Health Engineering Division, (ANG). Leadership and job performance in primary duty:
 1. Achieved Outstanding rating for 2009 Advanced Liaison (ADVON) Operational Readiness Inspections, in pursuit of state-of-art process improvement; chemical and physical hazards; beddown compliance; mission support.

2. Responsible for focused planning, coordinating, and managing the base Bioenvironmental Engineer section; liaison with civil engineering.
 3. Completion of surveys and evaluations of base installations and facilities that affect healthy well-being of military wing personnel.
 4. Working on North Carolina Air National Guard future; new building inspections and building upgrades; moving forward in compliance.
 5. Oversees the bioenvironmental Health Programs and findings involving chemical, and biological and physical stress factors within the work area.
 6. Determines health hazards with base operations and recommends engineering, administration, and protective control techniques.
 7. Expanded expertise; aiding with diagnostic and therapeutic service for flight medicine and environmental health.
 8. Leader and mentor to junior officers facilitating success with program management; increase leadership activities; building a strong 145th Medical Group.
- **Nov '87–Mar.'03:** Master Sergeant & NCOIC (manager); Radiological Technology Department. (ANG) Manager of department to support 1600 individuals for mission ready flying status.
- o Management of all department facets (supplies, equipment, repairs, scheduling, maintenance, training).
 - o Primary responsibility is to help maintain a mission ready force.
- Additional duties include:
- o Assisting other departments in achieving their responsibilities. Managed laboratory for 3 years.
 - o Physician Credentials Asst. Manager. (Discussed above)
 - o Drug testing – Helped maintain drug free force by 100% yearly testing for all individuals.
 - o Safety Manager – Maintained building and department safety codes. Provided quarterly inspections. Supported the needs of employers to obtained/maintain proper equipment.
 - o Ancillary training NCIOC – Managed all training platforms associated with non-warfare tasks. This training includes CPR, Geneva conventions, protection mechanisms, fire safety, operational security, communication security, ethics, etc.
- Unit Weapons Custodian – Responsible for weapons and munitions that are delivered to unit members.
- **Mar '84 – Nov. '87:** Sergeant; Radiological Technology department. Active duty evening supervisor.
- **Jan. 2006 – April '09:** ADMET Technologies, Inc., RTP, NC. (ADME/T applications)
 - **Oct '08 – April '09:** Regional Team Leader. Entrepreneurial activities to include collaborative health science, sales, marketing, facility, budgets, CRO support, and return company focus to support pharmaceutical drug developments and high throughput screening for human primary cells. World-wide cryopreserved cell distributions and distributor agreements. Employee salaries, reimbursement expenses and evaluations. Educating company partners on science, product, and market potentials.
 - **Jan '06 – Sept '08:** Manager Research and Development department for *in vitro* and *in vivo* biotechnologies. Utilizing human cells (adult, fetal, stem) – for pharmaceutical and toxicological applications. New generation bioengineered designs, culture inoculation, support structures, fiber technologies, and functional analysis for translational healthcare assays and devices.
 - **Nov. 2004 – Dec. 2005:** Consultant. Research applications for a Biomedical Company utilizing human liver cells (adult, fetal, stem) within 3D bioreactor devices. Culture inoculation, support structures, functional analysis. RTP, NC.

- **Jan. 2003 – Dec. 2005:** Research Associate / Post Doc.
 - **Jan '03 – Dec. '05:** Glaxo Lab within the Cellular and Molecular Physiology Lab. Univ. of NC - Chapel Hill, NC. Investigating 3D human stem cell tissue development for bioreactor designs, with a focus on extracellular matrix.
 - **Aug '03–Dec.'05:** Radiology Imaging Research Facility within the Bioengineering Division. Investigating in-vivo stem cell labeling and imaging to improve stem cell therapies. microMRI and microPET with cell transplantation expertise and in vivo cell therapy tracking. Duke University, Durham NC.
- **Aug 2002 – Dec 2002:** Post-doctoral researcher at the Cameron Applied Research Center within the Engineering of Biological Materials and Devices Laboratory. Univ. of North Carolina, Charlotte, NC. Investigated Liver bioreactor design scale-up. Micro and macro fluid flows with convection, diffusion, and dispersion. Fluid flow program analysis. Imaging and cell support.
- **Aug 1997 – Aug 2002:** Lecturer / Research assistant / Teaching assistant. Univ. of North Carolina at Charlotte, Charlotte, NC. Concentrated on Thermal-Fluid sciences while assisting undergraduates with FLUENT, a fluid-flow computer program.
- **Dec 1987 – Oct. 2000.** Radiological Technologist. Presbyterian Hospital, Charlotte, NC. Produce X-rays in routine, emergency, and surgical settings. Helped implement and supervise the Radiology addition of a Level II trauma center. Assisted with implementation of a Radiology department within a 250-bed satellite hospital. Participated in training radiology students appropriate “OJT” work skills. Obtained proficiency in CPR and First-aid.

EDUCATION

- Research Associate / Post Doc:** UNC Chapel Hill (Cell Physiology), Duke (Bioengineering Collaboration)
- 2002.** Ph.D in Mechanical Engineering and Engineering Science. Concentration in Biomedical Engineering: University of North Carolina at Charlotte. Charlotte, NC.
- 2002.** Masters in Mechanical Engineering and Engineering Science. Concentration in Biomedical Engineering University of North Carolina at Charlotte. Charlotte, NC.
- 1992.** B.S. in Mechanical Engineering. The University of North Carolina at Charlotte. Charlotte, NC.
- 1989.** Associate of Science, transfer degree. Central Piedmont Community College. Charlotte, NC.
- 1988.** Associate of Science in Radiological Technology. Midwestern State University. Wichita Falls, TX.
- 1986.** National Certification in Radiological Technology, ID # 210010 Category R. American Registry of Radiological Technology. Minneapolis, MN.

PUBLICATIONS

Journals:

1. **McClelland R.**, Wauthier, E., Reid, L., Hsu, E. “Human Hepatic Stem Cell Expansion and Specificity Viral Cell Labeling for microPET Tracking”. (Prep – Oct. 2010).
2. Winnike J., Athos P., Wolak J., **McClelland R.**, Watkins P., Macdonald J. “Stable Isotope Resolved Metabolomics of Primary Human Hepatocytes Reveals a Stressed Phenotype”. (submitted, Oct. 2010)
3. **McClelland R.**, Wauthier, E., Tallheden, T., Barbier, C., Reid, L., Hsu, E. “In Situ Labeling and Magnetic Resonance Imaging of Transplanted Human Hepatic Stem Cells”. *Molecular Imaging and Biology* (Accepted, DOI: 10.1007/s11307-010-422-x, 2010).
4. **McClelland R.**, Wauthier, E., Zhang, L., Melhem, A., Schmelzer, E., Barbier, C., Reid, L. “Ex Vivo Conditions for Self-Replication of Human Hepatic Stem Cells”. *Tissue Engineering, Part C* (Volume 14,

Ver. 4, pg 341-351, 2008).

5. Seagle, C., Christie, M., Winnike, J., **McClelland, R.**, Ludlow, W., O'Connell, T., MacDonald, J. "High Through-put NMR Metabolomic Footprinting for Tissue Engineering". *Tissue Engineering, Part C* (Volume 14, Ver. 2, pg 97-105) 2008.
6. **McClelland R.**, Wauthier, E., Uronis, J., Reid, L. "Gradients in the Liver's Extracellular Matrix Chemistry from Periportal to Pericentral Zones: Influence on Human Hepatic Progenitors". *Tissue Engineering, Part A*. (Volume 14, Ver. 1, pg 59-70) 2008.
7. Schmelzer, E., Zhang, L., Bruce, A., Wauthier, E., Ludlow, J., Yao, H., Moss, N., Melhem, A., **McClelland, R.**, Turner, W., Kulik, M., Sherwood, S., Tallheden, T., Cheng, N., Furth, M., Reid, L. "Human Hepatic Stem Cells from Fetal and Postnatal Donors". *Journal of Experimental Medicine* (Volume 204, Version 8, pg 1973-1987) 2007.
8. Turner, W., Schmelzer, E., **McClelland R.**, Wauthier, E., Chen, W., Reid, L. "Human Hepatoblast Phenotype Maintained by Hyaluronan Hydrogels". *J. Biomedical Materials Research. Part B. Applied Biomaterials* (Volume 82, Ver.1, pg 156-168) 2007.
9. Sicklick, JK., Li, YX, Melhem, A., Schmelzer, E., Zdanowicz, M., Huang, J., Caballero, M., Fair, JH., Ludlow, JW., **McClelland RE.**, Reid, L., Diehl, AM. "Hedgehog Signaling Maintains Resident Hepatic Progenitors Throughout Life". *Am. J. Gastrointest Liver Physiol.* (Volume 290, Version 5, pg G859-G870. Epub 2005 Dec 1). 2006
10. **McClelland R.E.** and Coger R.N. "Effects of Enhanced O₂ Transport on Hepatocytes Packed within a Bioartificial Liver Device". *Tissue Engineering* (Volume 10, Number 1/ 2, pg 253-266) 2004.
11. **McClelland R.E.**, MacDonald J., and Coger R.N. "Modeling O₂ Transport within Engineered Hepatic Bioartificial Devices". *Journal of Biotechnology and Bioengineering* (Volume 82, Issue 1, pg 12-27) 2003.
12. **McClelland R.E.** and Coger R.N. "Use of Micropathways to Improve Oxygen Transport in a Hepatic System". *Journal of Biomechanical Engineering*, Vol. 122, no. 3 pp. 268-273) 2000.

Book Chapters:

1. Wauthier, E., Schmelzer, E., Turner, W., Turner, W., Zhang, L., LeCluyse, E., Ruiz, J., Turner, R., Furth, ME., Kubota, H., Lozoya, O., Barbier, C., **McClelland, R.**, Yao, HL., Moss, N., Bruce, A., Ludlow, J., and Reid, L. "Hepatic Stem Cells and Hepatoblasts: Identification, Isolation, and Ex Vivo Maintenance". *Methods in Cell Biology*. (J. Mather, editor) Volume 86, pg. 137-225. 2008
2. **McClelland R.** and Reid, L. "Principles of Regenerative Medicine". *Bioartificial Livers*. (A. Attala, R. Lanza, editors). Chapter 53. 2007.
3. Schmelzer E., Melhem A., Zhang L., Yao H., McClelland R., Wauthier E., Turner W., Gerber D., Gupta S., Reid L. "Adult Tissue Stem Cells". *Hepatic Stem Cells and the Liver's Maturational Lineages" Implications for Liver Biology, Gene Expression and Cell Therapies*. (C. Potten, R. Clarke, J. Wilson, A. Renehan, editors). Taylor and Francis: Pg 161-214. 2006.
4. **McClelland R.**, Dennis R., Reid L., MacDonald J. "Tissue Engineering". *Introduction to Biomedical Engineering*. (J. Enderle, S. Blanchard, J. Bronzino, editors). Elsevier: Chapter 7, pg 313-400 (2005).

Patents

- Hepatic progenitor cell and method of isolating same. Serial number 12/431,440. Final signature Dec. 2009
- Methods of Isolating, Propagating, and Differentiating Hepatic Progenitor Cells. Under review 2009
- Paracrine Signals from Mesenchymal Feeder Cells and Regulating Expansion and Differentiation of Hepatic Progenitors Using Same. Serial number 12/213,100: 13 June 2008.
- US Provisional Application No. 60/736,873: Extracellular Matrix Components for Expansion and Differentiation of Hepatic Progenitors. US complete application No 11/560,049 on 15 Nov. 2006.

Magazine

<http://www.rt-image.com/1017stemcell>. RT Image, Vol. 18, No. 42, Oct. 17, 2005

ACTIVITIES AND AWARDS

Civilian

2001: Cameron Applied Research Award Nominee, UNC Charlotte.

1997-1998: University Research Associate Fellow. William States Lee College of Engineering. UNCC. Charlotte, NC

1997: Recipient of 10-year longevity award for professional service. Presbyterian Hosp., Charlotte, NC.

1993,1994,1995,1996: Recipient of the Outstanding Staff Member. Presbyterian Hospital (Radiology dept.), Charlotte, NC

Military

2010: Meritorious service award; demonstrating outstanding service among fellow officers.

2009: National award: Bioenvironmental Officer of the Year.

2009: Recognized by active duty military Operational Inspection Readiness (ORI) as outstanding support for contributions supporting North Carolina ANG – Medical Unit. (4-of-4 outstanding grades).

2007: Recognized by Inspector General (IG) for significant contributions supporting North Carolina Air National Guard. Credentials, SIDS, Bioenvironmental Engineering. Medical Unit.

2006: Awarded Master Craftsman; Radiology

2002: Awarded National Defense Service Medal. Medical Unit. Air National Guard, Charlotte, NC

2002: Voted Outstanding Airman of the Quarter by Executive Council and Peers. ANG, Charlotte, NC.

1995: Safety Award for promoting “SAFETY” public awareness. Air National Guard, Charlotte, NC.

1990, 1986: Decorated as Outstanding Organization Medical Member. Air National Guard, Charlotte, NC.

1993, 1990, 1987: Recipient of Conduct Medal. Air National Guard, Charlotte, NC.

1989, 1995: Obtained Expert Marksmanship medals. Air National Guard, Charlotte, NC.

AFFILIATIONS:

ASME, American Registry of Radiological Technology, NC National Guard Association.