

Carolina Express User Guide

Introduction	2
Carolina Express Approval	3
Business Plan Review Procedures	3
Carolina Express Operations	4
Management and Communications	4
Patent Prosecution Procedures	4
References	6
Appendices	7
A. Business Plan Review Criteria	7
B. Milestone Proposal	8
C. Carolina Express License Term Sheet	9

INTRODUCTION

The University of North Carolina at Chapel Hill actively supports the development of new ideas that have commercial opportunities or societal impact. The Office of Commercialization and Economic Development (OCED) strives to facilitate the translation of new discoveries into useful products and to ensure that these products are widely available. In some instances, an innovation can best be developed by a startup company incorporated for that very purpose.

Starting a company based on technology licensed from UNC-Chapel Hill has become easier as a result of the Carolina Express License Agreement, a fundamental departure from “business as usual” on the academic campus. The Carolina Express License Agreement is a license agreement that is fair and reasonable to the startup company and UNC-Chapel Hill and that a business attorney could advise their startup clients to sign without reservation or negotiation. It may be used if the following conditions are met:

- A UNC-Chapel Hill faculty, student, or staff is a founder of the company
- All intellectual property rights are owned solely by UNC-Chapel Hill¹
- A detailed business plan is reviewed and approved by UNC-Chapel Hill
- The agreement is executed without modification

Faculty and staff at UNC-Chapel Hill and individuals throughout the local business community spent a tremendous amount of effort on this process because they believe the Carolina Express License Agreement will:

- Facilitate deal flow, make the licensing process for faculty startup companies more efficient shortening the timeline and minimizing company's legal costs
- Allow the startup company:
 - to spend its time and effort on company matters such as securing financing and management rather than negotiating with UNC-Chapel Hill
 - maximum use of its funding for early R&D by back loading consideration owed to UNC-Chapel Hill
 - to function independent of the University, especially for issues related to university approvals for sublicense agreements
- Encourage more entrepreneurial efforts on campus and foster a collaborative spirit between OCED and the faculty, students and staff who start companies
- Be a tool to recruit faculty to UNC-Chapel Hill who are interested in entrepreneurial activities
- Make UNC-Chapel Hill-based spinouts very attractive to venture backed investors and other commercialization partners
- Amplify the impact that Carolina has on economic development and improving the health and well-being of society

¹ Where intellectual property rights are jointly owned the Carolina Express License Agreement may be used where the joint owner is willing to accept the terms.

UNC-Chapel Hill startup companies are not required to use the Carolina Express License Agreement. OCED will engage in the traditional negotiation process with a potential startup company if it desires to do so. However, regardless of whether or not the startup company elects the Carolina Express License Agreement, the following guidelines and procedures will be followed.

New Enterprise Opportunity (NEO) companies also use the Carolina Express License Agreement however the exit fee is waived in lieu of the company equity UNC- Chapel Hill receives under the NEO program. NEO companies are expected to otherwise comply with all of the application requirements including submission of a business plan.

CAROLINA EXPRESS APPROVAL

BUSINESS PLAN REVIEW PROCEDURES

Use of the Carolina Express License is contingent upon the submission of a Carolina Express Business Plan Application and approval of that plan by UNC. OCED will evaluate the business plan and make the final approval decision. (see also review criteria in Appendix A and suggested Milestones in Appendix B)

Your primary point of contact will be the OCED technology development manager who is handling the intellectual property being licensed to the company.

OCED will endeavor to complete their review within two weeks of submission of a complete package. The package can be submitted concurrent with or prior to completion of Conflict of Interest Review but final approval will be contingent upon notice of satisfactory completion of Conflict of Interest review. Providing advance notice of your intent to submit a business plan for approval will allow OCED to plan ahead and schedule the necessary meetings.

Information to be submitted for review:

- Completed Carolina Express Business Plan/Application (provided by company, a separately formatted business plan should be included if available but is not required) NOTE: OCED LINK.
- Notice of satisfactory completion of Conflict of Interest review (from UNC-Chapel Hill inventors² who will receive equity as a founder of the company). COI review should be initiated early in the company formation process in order to allow sufficient time for review. Submit a COI report at <https://apps.research.unc.edu/air/>.
- Signed Acknowledgement and Waiver (signed by UNC-Chapel Hill inventors² who will receive equity as a founder of the company, form provided by OCED technology manager).
- Signed University Inventor Statement (signed by UNC-Chapel Hill inventors² who will receive equity as a founder of the company, form provided by OCED technology manager).

² Any UNC employee or affiliate named as an inventor on any of the patents (or as an author on any copyright) to be licensed to the company

CAROLINA EXPRESS OPERATIONS

MANAGEMENT AND COMMUNICATIONS

The primary and first point of contact for matters related to the license at UNC-Chapel Hill is the OCED technology development manager, and at the company contact should be the CEO or his/her designate. The UNC-Chapel Hill faculty member who is the founder of the company should not be the primary point of contact for the company.

It is expected that the OCED technology development manager and company management will meet either in person or via conference call on a regular basis. Any decisions or matters that cannot be managed directly by the OCED technology development manager will be addressed by the OCED management team and/or the Vice Chancellor for Commercialization and Economic Development.

The OCED technology development manager can help with matters including but not limited to the following:

- Collecting documents for due diligence
- Acting as an interface between UNC-Chapel Hill and the company
- Transfer of materials between UNC-Chapel Hill and the company
- Intellectual property matters related to company sponsored research
- Verification that company is not in breach of the license agreement

PATENT PROSECUTION PROCEDURES

Throughout the life of the Carolina Express License patent prosecution will require ongoing communication between OCED and the company. UNC-Chapel Hill utilizes outside counsel for patent prosecution, counsel is managed by OCED with the company providing guidance and comment as needed. Patent attorneys engaged by UNC-Chapel Hill must be approved by the State of North Carolina Attorney General's Office.

Legal Representation:

- All patent applications will be filed on behalf of and managed by UNC-Chapel Hill.
- All official correspondence will be directed to OCED with a copy provided to the company designee.
- The company designee (or their counsel) may communicate directly with prosecution counsel, however counsel will take action only upon receiving instructions from OCED.
- Use of UNC-Chapel Hill patent prosecution counsel for representation on company matters represents a conflict of interest for the attorney and as such UNC-Chapel Hill requires that the start-up company does not use the UNC-Chapel Hill patent prosecution counsel for company matters. Requests for exemptions from this standard practice will be evaluated on a case by case basis.

Financial Management

- All attorney invoices for patent prosecution expenses will be directed to UNC-Chapel Hill
- On a monthly basis, UNC-Chapel Hill will forward the original attorney invoices to the company and invoice the company for reimbursement of these expenses.
- Invoicing for past and ongoing patent prosecution expenses will begin immediately upon execution of the Carolina Express License; however, since licensees using the Carolina Express License are not required to reimburse these costs immediately, the invoice will simply note the actual payment due date. After deferral period, these expenses will be due within 30 days of receiving the invoice.
- Questions regarding payments or invoices should be directed to Judith Whitford at OCED (phone: 919.966.3929; email: license@unc.edu).
- Failure to pay amounts due, including reimbursement of patent prosecution expenses within thirty days of receipt of a UNC-Chapel Hill invoice, is a material breach of the License Agreement. In accordance with Section 7.3 of the Agreement the License will be terminated if the company does not enter into a payment plan or correct the deficiency within sixty days.
- Payment plans may be negotiated with UNC-Chapel Hill on a case by case basis where a company can document insufficient funds and accepts the conditions set forth in the agreement for extended payments.
- Companies unable to meet payment requirements will be granted the opportunity to present an alternate plan to a team of evaluators prior to termination for non-payment.

Filing of New Patent Applications

- OCED will honor all requests from the company to file new or continuing patent applications so long as the company is actively and timely reimbursing patent prosecution expenses.
- Requests from the company to file new or continuing US patent applications while the company is in a deferral period and not actively reimbursing patent prosecution expenses will be considered on a case by case basis; foreign patent applications will not be filed without advance payment of filing expenses while the company is in a deferral period.

Patent Prosecution

- OCED will defer to the company in making patent prosecution decisions so long as the decision elected by the company is not in conflict with UNC-Chapel Hill interests and the company is actively and timely reimbursing patent prosecution expenses.
- OCED will make decisions on patent prosecution while the company is in a deferral period and not actively reimbursing patent prosecution expenses.
- In accordance with Section 8.3 of the Agreement, if the company elects to abandon patents, applications, or claims and such abandonment is deemed to not serve UNC-Chapel Hill's interests, the patents and/or applications will be maintained at UNC-Chapel Hill expense and excluded from the License Agreement by amendment.

REFERENCES

Office of Commercialization and Economic Development

[Link to OCED here](#)

Conflict of Interest Policy

<http://research.unc.edu/offices/coi/>

Use of University Resources in Support of Entrepreneurial Activities

http://research.unc.edu/offices/vice-chancellor/policies-issues/data_vcred_entrep_sp/

Patent and Invention Policy

<http://policy.sites.unc.edu/files/2013/05/Patent-Invention.pdf>

Copyright Policy

<http://policies.unc.edu/files/2013/05/Copyright.pdf>

Equity Acquisition in Technology Licensing

<http://policies.unc.edu/policies/equity/>

External Professional Activities for Pay

<http://policies.unc.edu/policies/external-activities/>

Kenan-Flagler Business School

UNC-CH Launching the Venture Course

<http://www.kenan-flagler.unc.edu/entrepreneurship/programs/launching-the-venture>

Entrepreneurial Resources in North Carolina

Council for Entrepreneurial Development

<http://cednc.org>

North Carolina Biotechnology Center

<http://www.ncbiotech.org>

North Carolina Small Business Technology Development Centers

<http://www.sbtcdc.org>

APPENDIX A
CAROLINA EXPRESS BUSINESS PLAN REVIEW CRITERIA

Organizational Plan/Management Team

- Type of legal entity
- Advisors (bio for those already on board and skill/knowledge profile for those still needed)
- Management Team (bio for those already on board and skill/knowledge profile for those still needed)

Opportunity

- The product(s) and their place in the market (market needs, size, share, competition, etc)
- The intellectual property position (barriers to entry)
- The product development status
- Business model (e.g., technology licensor, product development, channels/alliances, customers, competitive advantage, sustainability, etc.)

Assessment of Risk/Milestones

- Major risks (including technical, regulatory, competition, etc.)
- Variables and level of uncertainty that might lead to risks occurring
- Contingency plan if a risk occurs

Development/Financial Plan

- Requirements and timeline to first commercial sale
- Technical capabilities (both available and plan for obtaining those still needed)
- Facilities (both available and plan for obtaining those still needed)
- Partnering and/or recruitment plans if applicable
- Budgets/Cash Flow (both operational and capital) for 3-5 years
 - Consulting and/or Salaries
 - Regulatory
 - Rent
 - Patents
- Sources of funding (both available and plan for obtaining that still needed)
- Exit strategy if applicable

APPENDIX B

MILESTONE PROPOSAL

Prior to execution of the Carolina Express License, milestones must be defined and inserted into Appendix B of the Agreement. Milestones should be proposed by the company consistent with an approved business plan and should at minimum include the following:

1. Licensee shall have a corporate management team in place by _____

2. Licensee shall have financing sufficient to meet the obligations under this License Agreement within one years after the Effective Date 3. Licensed Product Development Milestones (generally based on construction and testing of prototype and/or stages of regulatory approval)

(i) subject matter/date

(ii)

(iii)

(iv)

4. Licensee shall commence with commercial sales of License Product by _____

While milestones are intended to serve as measurable development benchmarks it is understood that unexpected delays may occur and OCED is generally willing to re-negotiate milestones upon demonstration of good faith attempts to solve such problems.

APPENDIX C

CAROLINA EXPRESS LICENSE TERM SHEET

PREREQUISITES:

- The intellectual property rights are owned solely by UNC.
- UNC approves the Company's (i) detailed business plan indicating Company's strategies to develop and commercialize the technology and (ii) financial, product development and sales Milestones.
- At least one UNC faculty, student or staff is a company founder.
- UNC founder relinquishes his/her rights to receive an inventor's share from License Fee, if founder has received equity in the company.

LICENSE TERMSⁱ:

Grant

Exclusive, worldwide, all fields with the right to sublicense (unless agreed to otherwise), limited by and subject to the rights and requirements of the United States Government. UNC reserves the rights to practice the intellectual property rights for research and teaching.

Consideration

Patent Expenses:

- Company will reimburse University for patent expenses incurred prior to the first anniversary of the Effective Date with payments to begin one hundred and eighty (180) days after the Effective Date with a minimum monthly payment of five hundred dollars (\$500.00) or ten percent (10%) of Past Patent Costs, whichever is less.
- Company will reimburse University for patent expenses incurred after the first anniversary of the Effective Date within 30 days of receiving a monthly invoice for such patent expenses.

License Fee:

- In lieu of an upfront license fee, Company shall have a contractual obligation to make a cash payment to University in the amount equal to 0.75% of the Company's fair market value at the time of a Liquidation Eventⁱⁱ (e.g. IPO, asset sale, merger or acquisition)

Royalty:

- % of Net Sales of a Clinically-Approved Productⁱⁱⁱ
- 2.0 % of Net Sales of an Other Product^{iv}

Sublicensing:

- 10% of Sublicensing Revenue^v
- 20% of Sublicensing Royalty Revenue^{vi}

Annual Maintenance Fee:

Paid yearly	Clinically-Approved Product	Other Product
Beginning after 3 calendar year	\$15,000	\$5,000
Beginning after 6calendar year and each calendar year thereafter	\$30,000	\$10,000

Anti- Stacking: Yes, no less that 50% of royalty/payment owed to UNC

Combination Product: Yes

Milestone Payments: None

Additional Terms:

Global Access Rights: Mandatory sublicensing

Due Diligence: Performance milestones required

Governing Law and Venue: The law of North Carolina and federal or state courts of North Carolina.

Publication Review: Company has 45 days to review prior to publication until first actual publication of the Patent Rights

Indemnification: Company indemnifies UNC for any UNC losses resulting from Company's use of patent

Infringement: Company has the first right to defend against infringement claims

Insurance: Company must be adequately insured to cover its liabilities under the license.

Patent Filing/Prosecution: Controlled by UNC however directed by Company

Reporting: Yearly progress reports through the life of the license, quarterly Royalty Reports

Termination: UNC may terminate for material breach if not cured within 60 days

Warranties and Representations: UNIVERSITY DISCLAIMS ALL WARRANTIES WITH REGARD TO PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT. UNC makes no representation that any patent will issue, will not infringe rights of third parties, or of the validity of any patent included in the Patent Rights.

ⁱCompanies are under no obligation pursue a license through the use of this agreement, however for those that elect to do so this license agreement will be executed without modification.

ⁱⁱ**"Liquidation Event"** means a (i) a merger, share exchange or other reorganization ("Merger"), (ii) the sale by one or more stockholders of a majority of the voting power of the Licensee ("Stock Sale") or (iii) a sale of all or substantially all of the assets of the Licensee (or that portion of its assets related to the subject matter of this Agreement) ("Asset Sale") in which for (i), (ii), and (iii) above, the stockholders of the Licensee prior to such transaction do not own a majority of the voting power of the acquiring, surviving or successor entity, as the case may be. Notwithstanding the foregoing, a Liquidation Event shall not include a bona fide financing transaction in which voting control of the Licensee transfers to one or more persons or entities who acquire shares of Licensee capital stock from Licensee in exchange for either an investment in Licensee or the cancellation of indebtedness owed by Licensee, or a combination thereof.

ⁱⁱⁱ**"Clinically-Approved Product"** means any Licensed Product for which (i) FDA approval or clearance (or any foreign equivalent thereof), which is granted or withheld on the basis of the results of human clinical trials of such Licensed Product, is required prior to sale of such Licensed Product for human therapeutic, diagnostic, or prophylactic use, or for such Licensed Product's use as a human medical device and (ii) the costs directly related to conducting such human clinical trials incurred by Licensee or any Affiliate or Sublicensee are greater than one million dollars (\$1,000,000).

^{iv}**"Other Product"** means any Licensed Product that is not a Clinically-Approved Product.

^v**"Sublicensing Revenue"** means any consideration actually received by Licensee or an Affiliate from a third party as consideration for the grant of rights to Patent Rights (net of any tax or similar withholding obligations imposed by any tax or other government authority(ies) that are not reasonably recoverable by Licensee). Sublicensing Revenue includes, but is not limited to, upfront fees, license maintenance fees, and milestone payments, or other payments, including the fair market value of any non-cash consideration, received by Licensee in consideration for any rights granted to Patent Rights under a sublicense agreement, and excludes (i) Sublicensing Royalty Revenue, (ii) purchases of equity or debt of Licensee or any Affiliate, (iii) fair market value payments made in connection with research and development agreements, joint ventures, partnerships or collaboration agreements where Licensee or an Affiliate is obligated to perform research and development of any Licensed Product(s), (iv) the grant to Licensee of intellectual property rights related to the technology described in the Patent Rights, and (v) other payments made by a Sublicensee as consideration for Licensee's or an Affiliate's performance of services or provision of goods, provided such services or goods are not Licensed Products or, if such services or goods are Licensed Products, (a) the provision of such services or goods results in Net Sales pursuant to which a royalty is payable under Section 3.4 or (b) the provision of such services or goods constitutes one or more of the following: (1) the distribution of reasonable quantities of promotional samples of Licensed Products or (2) the provision of Licensed Products for clinical trials, research purposes, or charitable or compassionate use purposes.

^{vi}“**Sublicensing Royalty Revenue**” means sales-based royalties, sales milestone payments, other payments calculated on the basis of sales, and minimum sales royalties actually received by Licensee or its Affiliate from a third party as consideration for the grant of rights to Patent Rights (net of any tax or similar withholding obligations imposed by any tax or other government authority(ies) that are not reasonably recoverable by Licensee).