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INTRODUCTION

The University of North Carolina at Chapel Hill (UNC) actively supports the development of new ideas that have potential commercial or societal impact. The Office of Technology Commercialization (OTC) 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.

In 2009, UNC implemented the Carolina Express License Agreement (**CELA**), a fundamental departure from "business as usual" on the campus at the time. Today, many other universities have implemented their version of an "express" license. Since its implementation, the CELA has been executed by over 70 UNC startup companies and many other universities have followed UNC's lead and implemented their own version of "express" licensing. The life science and therapeutics markets have evolved significantly since 2009 and for the first time OTC is adjusting the financial terms of the CELA to better align with the current market financials and license comps. The CELA 2021 has the same advantages of the original CELA and became available to UNC startup companies on May 1, 2021.

The CELA 2021 is a license agreement that is fair and reasonable to both the startup company and UNC and that a business attorney could advise their startup company clients to sign without reservation or negotiation. OTC reserves the right to limit the availability of the CELA 2021 in certain situations (details below).

The primary goals of the CELA 2021 are to:

- Facilitate deal flow, make the licensing process for faculty startup companies more efficient by shortening the negotiation timeline and minimizing the startup 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,
    - maximize use of its funding for early R&D by back loading license payments owed to UNC, and
    - function independently of UNC, especially with respect to sublicensing.
- Encourage more entrepreneurial efforts on campus and foster a collaborative spirit between UNC and the faculty, students and staff who start companies.
- Be a tool to recruit faculty to UNC who are interested in entrepreneurial activities.
- Make UNC-based startup companies very attractive to venture backed investors and other commercialization partners.
- Amplify the impact that UNC and the State of North Carolina have on economic development and improving the health and wellbeing of society.

The CELA 2021 may be used if the following conditions are met:

- A detailed business plan application is reviewed and approved by UNC.
- All intellectual property rights are owned solely by UNC, or
- Intellectual property rights are co-owned by UNC and another party, and the other party agrees to the terms of the CELA 2021
- The license agreement is executed without modification

OTC may limit its use of the CELA 2021 in situations where UNC has significantly contributed to the development or validation of the UNC technology prior to licensing. The contributions may include clinical or prototype validation or funding from OTC or academic units (e.g., for technology development or support of a large patent portfolio), the Eshelman Institution for Innovation, the Lineberger Cancer Center, the Vice Chancellor for Research, the Chancellor's initiatives, or other similar funding. Increased financial terms will be appropriate when such investments have been made by UNC.

Eligible UNC startup companies are not required to use the CELA 2021, and OTC will engage in the traditional, market-based negotiation process with a potential startup company upon request. Regardless of whether the eligible startup company elects the Carolina Express License Agreement, the guidelines and procedures outlined below will be followed.

CAROLINA EXPRESS APPROVAL

BUSINESS PLAN REVIEW PROCEDURES

Use of the CELA 2021 is contingent upon the submission of a Carolina Express Business Plan Application or equivalent company business plan and approval of that plan by OTC. A review committee will evaluate the business plan and make the final approval decision (see review criteria in Appendix A and suggested Milestones in Appendix B).

The primary point of contact for the review committee will be the OTC commercialization manager who is managing the intellectual property being licensed to the startup company.

OTC and the review committee will endeavor to complete their review within two weeks of submission of a complete application package, which must include (i) a completed Carolina Express Business Plan Application, (ii) notice(s) of satisfactory completion of Conflict of Interest (COI) review, (iii) signed Acknowledgmentand Waiver(s), and (iv) signed University Inventor Statement(s).

While the package can be submitted before or during completion of COI review, final approval will be contingent upon notice of satisfactory completion of COI review. Providing advance notice of your intent to submit a business plan application for review will allow the review committee to plan and schedule the necessary meetings.

The Review Committee is comprised of:

- The Vice Chancellor for Innovation, Entrepreneurship and Economic Development,
- Office of Technology Commercialization (Director of Technology Commercialization, Director of Licensing, and all commercialization managers),
- Kickstart Venture Services (all members), and
- Ad hoc participants where subject matter expertise is desired

The completed Carolina Express Business Plan Application must be provided by the startup company, and an application form is available at https://otc.unc.edu/startups/kickstart-venture-services/. If available, a separately formatted business plan or slide deck should be included but is not required.

A notice of satisfactory completion of COI review must be submitted by all UNC Inventors who will receive equity as a founder of the startup company. An Inventor is 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. COI review should be initiated early in the startup company formation process to allow sufficient time for review. To initiate COI review, submit a Self-Initiated Conflict of Interest Disclosure via AIR at https://apps.research.unc.edu/air/. The project title should be "OTC license to <<Startup Company Name>>", and your role should be entered as "PI", and the startup company should be entered as "Sponsor". Failure to initiate COI review in a timely manner may result in delays.

If you are a company founder holding equity in the startup company and you will be engaging in external activities with or for the startup company (such as raising money, consulting, advising, etc.), then you will need to submit a Notice of Intent to Engage in EPAP Disclosure in AIR as well at https://apps.research.unc.edu/air/. Your equity in the startup company is considered compensation/pay for the work you are doing for the startup company regardless of its current monetary value. If you have any questions about completing these disclosures, please call the COI office at 919.843.9953 or email them at coi@unc.edu.

Lastly, the Acknowledgement and Waiver (attached in Appendix C) and University Inventor Statement (attached in Appendix D) must be signed and submitted by all UNC employees who will receive equity in the startup company.

CAROLINA EXPRESS OPERATIONS

MANAGEMENT AND COMMUNICATIONS

The primary points of contact for matters related to the license agreement is the OTC commercialization manager at UNC and the CEO or his/her designate at the startup company. A UNC employee who is the founder of the startup company should not be the startup company's point of contact with OTC for matters related to the license agreement.

It is expected that the OTC commercialization 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 OTC commercialization manager will be addressed by the OTC Directors and/or the Vice Chancellor for Innovation, Entrepreneurship and Economic Development.

The OTC commercialization manager can help with matters such as:

- Collecting documents for due diligence,
- Acting as an interface between UNC and the company,
- Transferring materials and information between UNC and the company,
- Managing intellectual property matters related to company sponsored research, and
- Verifying that the company is in compliance with the license agreement.

PATENT PROSECUTION PROCEDURES

Throughout the life of the license agreement, ongoing communication between OTC and the startup company will be required on patent prosecution issues. UNC uses external counsel for patent prosecution, and external counsel is managed by OTC with the company providing input and comment as needed. Patent attorneys must be approved by the State of North Carolina Attorney General's Office prior to engagement with UNC.

Legal Representation:

- All patent applications will be filed on behalf of UNC and managed by OTC.
- All official correspondence will be directed to OTC with a copy provided to the designated company representatives.
- The company representative may communicate directly with UNC patent counsel; however, UNC patent counsel will act only upon receiving instructions from OTC. UNC will not transfer control of patent prosecution to company's counsel.
- UNC does not allow the startup company to use the same patent attorney as UNC for representation on company matters due to the conflict of interest that scenario creates for the patent attorney.

Financial Management

- UNC's patent attorneys will send all invoices for patent filing, prosecution, and maintenance expenses directly to OTC.
- On a monthly basis, OTC's financial manager will forward the original attorney invoices to the company and invoice the company for reimbursement of these expenses.
- Invoicing for past and some ongoing patent prosecution expenses will begin upon execution of the CELA 2021; however, because the CELA 2021 allows the startup company to defer reimbursement of these costs for a defined period of time, the initial invoices will simply note the actual payment due date. After the deferral period, these expenses will be due within 30 days of receiving the invoice.
- Questions regarding payments or invoices should be directed to OTC's financial manager by phone at 919.966.3929 or email at license@unc.edu.
- Failure to pay amounts owed when due (including, but not limited to, reimbursement of patent prosecution expenses within thirty days of receipt of a UNC invoice, earned royalties, minimum royalties, and sublicensing revenue) is a material breach of the CELA 2021. In accordance with Section 7.3 of the CELA 2021, the License Agreement will be terminated if the company does not enter into an extended partial payment plan or correct the deficiency within sixty days.
- Extended partial payment plans may be negotiated with OTC on a case-by-case basis where a company can document insufficient funds and accepts the conditions set forth in Appendix C of the CELA 2021 for such extended payment plan.
- Companies unable to meet extended partial payment requirements will be granted the opportunity to present an alternate plan to OTC for consideration prior to termination of the CELA 2021 for non-payment of patent expense amounts owed when due.

Filing of Continuing Patent Applications

- When the company is actively and timely reimbursing patent prosecution expenses, OTC will honor requests from the company to file continuing US and foreign patent applications.
- When the company is in an approved payment deferral period and not actively reimbursing UNC for patent prosecution expenses, requests from the company to file continuing US applications will be considered on a case-by-case basis. Advance payment (at least 14 days prior to the filing deadline) of estimated costs will be required before OTC will file foreign applications.

Patent Prosecution

- When the company is actively and timely reimbursing patent prosecution expenses, OTC will defer to the company in patent prosecution decisions so long as the company's decision is not in conflict with UNC's interests.
- When the company is in an approved payment deferral period and not actively reimbursing UNC for patent prosecution expenses, OTC will make final decisions (with due consideration to company input) on patent prosecution. Advance payment (at least 14 days prior to the filing deadline) of estimated costs will be required before OTC will authorize further prosecution of foreign patent applications.
- In accordance with Section 8.3 of the CELA 2021, if the company elects to abandon patents, applications, or claims and such abandonment is in conflict with UNC's interests, the patents and/or

patent applications will be maintained and/or prosecuted at UNC's expense and such patents will be excluded from the License Agreement.

REFERENCES

Office of Technology Commercialization

OTC contact information
https://otc.unc.edu

Conflict of Interest Policies (personal and institutional)
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=131873
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=131874
https://apps.research.unc.edu/air/

Use of University Resources in Support of Entrepreneurial Activities
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=132343

Patent and Invention Policy
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=132139
https://apps.research.unc.edu/blue

Copyright Policy
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=132138

Equity Acquisition in Technology Licensing
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=132158

External Professional Activities
https://policies.unc.edu/TDClient/2833/Portal/KB/ArticleDet?ID=132160
https://apps.research.unc.edu/air/

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 Agreement, milestones must be defined and inserted into Appendix B of the License 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 in the amount of*_____*by*_____

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*_____
5. Sales milestones

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

APPENDIX C

ACKNOWLEDGEMENT and WAIVER

Company:
Individual:

In respect of the grant of a license to intellectual property rights (the "**License Agreement**") by the University of North Carolina at Chapel Hill ("**UNC**") to the company identified above ("**Licensee**"), I, as the individual identified above and as an inventor or creator of the licensed subject matter (the "**Technology**"), acknowledge and agree as follows:

(1) Ownership and all other rights to the Technology, including any such rights that I may have now or in the future, are governed by the patent and copyright policies of the University of North Carolina and The University of North Carolina at Chapel Hill.

(2) Pursuant to the License Agreement and/or an LLC agreement between UNC and Licensee, UNC has received or expects to receive one or more of the following: 1) a percent ownership interest in Licensee, 2) shares of stock issued by Licensee, and/or 3) a Contractually Obligated Fee in Lieu of a License Fee upon a Liquidation Event or Initial Public Offering (collectively "**UNC Equity**").

(3) I acknowledge that as a founder of the Licensee, I will receive or have received an ownership interest directly from the Licensee ("**Founders Equity**"). Consequently, I confirm that the receipt of such Founder's Equity satisfies in full my right (and that of my heirs, successors, or assigns) to receive a distribution of UNC Equity, and discharges UNC's duty under its policies to share with me any UNC Equity, or proceeds received by UNC from the sale of UNC equity.

(3) I hereby acknowledge that counsel for UNC represent the interests of UNC and not my interests with respect to the tax consequences of any consideration I receive from the Licensee or from UNC. I further acknowledge that I have not received any tax advice from UNC, and that I have been advised by representatives of UNC to consult with independent tax counsel of my own choosing regarding the federal, state and local tax consequences to me regarding the receipt of Founder's Equity or other consideration from the Licensee or pursuant to the terms of, the patent and copyright policies of UNC.

(4) I make this ACKNOWLEDGEMENT and WAIVER freely and of my own accord and without duress.

_____
[signature][date]

_____County, North Carolina

I certify that the following person(s) personally appeared before me this day, acknowledging to me that he or she has signed the forgoing document:

Assignor Name

Notary Public Name: SEAL

My Commission Expires:

APPENDIX D

STATEMENT OF UNIVERSITY INVENTOR

Name:
Licensed Technology:
Company:

Because of the license granted or to be granted by the University of North Carolina at Chapel Hill ("**UNC**") to the Company identified above ("**Licensee**") and in light of my significant financial interest in the Licensee, I acknowledge the potential for a conflict of interest between the performance of my research, teaching, and administrative obligations at UNC and my personal financial interests as well as my contractual and other obligations to the Licensee. Therefore, I will not:

(i) Involve myself, students or post-doctoral fellows in research and development projects for the Licensee, including human subjects research, without obtaining appropriate approval(s) of my department, dean(s), and/or conflict of interest committee; and/or
(ii) Restrict or delay general access to information from UNC research; and/or
(iii) Alter the scope or direction of my UNC research in order to materially benefit the Licensee; and/or
(iv) Attempt to influence UNC business decisions on behalf of the Licensee.

I affirm that I have read, understood and will comply with the UNC Policies on External Professional Activities for Pay, Conflicts of Interest and Commitment, and Acquisition of Equity in Licensing Transactions, as they may be amended from time to time. I understand and acknowledge that my compliance with these policies is a condition of my employment at UNC.

To avoid the appearance of a conflict, I will at all times attempt clearly to differentiate between the intellectual directions of my UNC research and my contributions to the Licensee. I understand that given the potential conflict of interest, as determined by the Dean or other relevant UNC administrator, in some circumstances UNC may not accept sponsored research funding on my behalf from the Licensee. If UNC accepts sponsored research funding on my behalf from the Licensee, I will initiate and conduct such research only as allowed under the Policy on Conflicts of Interest and Commitment and any disclosure, monitoring or management procedure imposed pursuant to that Policy.

I acknowledge that it is my responsibility to obtain my own financial, tax and legal advice in regard to any equity or proceeds of equity that I may receive.

Finally, I understand that I must disclose my significant financial interest in the Licensee in all publications or public statements I make presenting research related to this license.

Signature of Inventor:_____Date: _____

Inventor's Department Head:_____Date:_____
(faculty supervisor for staff, student, and post-doc inventors)

APPENDIX E
CELA 2021 TERM SHEET

PREREQUISITES:

- The intellectual property rights are owned solely by UNC (or co-owned with approval from co-owner and 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 of the License Fee if founder has received equity in the company.

LICENSE TERMS[i]**:**

Grant

Exclusive, worldwide, in the licensed field 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 UNC for patent expenses invoiced to UNC prior to the first anniversary of the Effective Date with payments to begin 180 days after the Effective Date with a minimum monthly payment of $500.00. Company will reimburse such past patent expenses in full within thirty (30) days of the first anniversary of the Effective Date.
- Company will reimburse UNC for patent expenses invoiced to UNC 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 UNC in the amount equal to 1.0% of the company's fair market value at the time of a Liquidation Event[ii](e.g., IPO, asset sale, merger, or acquisition) ("Exit Fee")
- The Exit Fee will convert[iii] to 5.0% equity in the company at the time the company secures $2M in Initial Financing[iv].

Royalty:

2.0 % of Net Sales of a Clinically-Approved Product[v]
3.0 % of Net Sales of an Other Product[vi]
5.0% of Net Sales of Service Product[vii]

Sublicensing:

- 15% Sublicensing Revenue[viii] or
- 10% if the sublicense is executed for a Clinically-Approved Product following the completion of a Phase I or I/II clinical trial for that product

Annual Maintenance Fee:

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

Anti- Stacking: Yes, payment to UNC may be no less than 50% of the royalty owed

Combination Product: Yes

Milestone Payments: None

Additional Terms:
Participation Rights: Right for UNC or its assignee to invest in future funding rounds.
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.
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.

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[i] Companies are under no obligation to use the CELA 2021; however, for those that elect to do so, the CELA 2021 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 amajority 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] Where the Exit Fee has been converted to equity and this Agreement is assigned under an Asset Sale to a non-Affiliate third party, Licensee will pay University a transfer fee equal to one percent (1.0%) of the sum of all cash and the fair market value of all property payable to Licensee at the time of the transaction,and the sum of all cash, and the fair market value of all property for Trailing Consideration payable to the Licensee, when and if, actually paid.

[iv] "**Initial Financing**" means Licensee's initial receipt of at least two million dollars ($2,000,000) of cumulative total of cash or cancellation of indebtednessin exchange for the issuance of Equity Securities.

[v] "**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 humantherapeutic, 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).

[vi] "**Other Product**" means any Licensed Product that is not a Clinically-Approved Product or a Service Product.

[vii] "**Service Product**" means a Licensed Product that is a service provided by Licensee, Affiliate or Sublicensee. Research and development carried out by Licensee, Affiliates, or a Sublicensee for the purpose of creating Clinically-Approved Products or Other Products does not constitute a Service Product.

[viii] "**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 or Copyrights (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 or Copyrights under a sublicense agreement, and excludes (i) sales based royalties due under Section 3.7, (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 or Copyrights, 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 3.7 or (b) the provision of such services or goods constitutes one or more of the following: (1) the distribution of reasonablequantities of promotional samples of Licensed Products or (2) the provision of Licensed Products for clinical trials, research purposes, or charitable or compassionate use purposes.