

Application Cover Memo

- Use the optional [Application Cover Memo](#) textbox to convey information that cannot be accommodated by the Application.
- With each review, the previously posted Cover Memo is erased to allow for composition of a new Cover Memo.

Note: Because this field is optional, the Cover Memo section in the [Item List](#) is pre-checked (green check mark is always present).

Historical Cover Memos are date/time stamped, stored, and displayed, chronologically, atop the dynamic pdf version of the application, accessible, here:

This section serves as a cover memo from the Investigator to the IRB, if needed. Provide any additional information here that is not already addressed above. You are not

Application Cover Memo:

UNC owns the s-IOT technology, because it was invented by UNC faculty (Drs. Mol and Platin) as part of research and they were not paid outside of their UNC salaries. UNC faculty, but those faculty are not listed on the IRB application.

Recorded by [Teresa Etscovitz](#) on 05/02/2016 at 11:19 AM

To navigate the Application, press any link in the Item List to your left.

[Save and Continue](#)

Application Cover Memo

Cover memo prepared by Enrique Platin on 04/13/2016 at 11:43 AM
Modified by Teresa Etscovitz on 04/22/2016 at 06:26 PM

Study # 14-2700 was a bench top study that evaluated the feasibility of using a stationary intraoral tomosynthesis system (s-IOT) using carbon nanotube (CNT) field-emission X-ray technology for the diagnosis of interproximal caries. The study compared the experimental s-IOT with conventional 2D intraoral imaging for primary proximal caries detection. The proposed study has the same objective but is a patient study using a prototype system that was specifically designed for dental applications.

This is an Investigational Device study involving an x-ray-producing intraoral system developed by Drs. Mol and Platin in conjunction with other faculty at UNC-CH. These other faculty are not engaged in the research. The system is manufactured by Xinray, Inc., located in the Research Triangle Park.

The Investigators are not conducting this study for pre-marketing purposes; therefore, a pre-market application is not required to be submitted to the FDA.

The radiographic technologist and research coordinator referred to in this application have yet to be identified/hired for this research study; thus, they have not yet been named in the research personnel section. They will be added with a modification to this application. Until that time, only qualified research personnel listed in the IRB application will conduct study procedures.

Application Cover Memo

Cover memo prepared by Teresa Etscovitz on 05/02/2016 at 11:19 AM

UNC owns the s-IOT technology, because it was invented by UNC faculty (Drs. Mol and Platin) as part of research and they were not paid outside of their UNC salaries. The company that manufactures the s-IOT device is owned by several UNC faculty, but those faculty are not listed on the IRB application.

Application Cover Memo (2)

All required sections of the application must be completed prior to saving the cover memo. If you receive this message, return to the item list to complete all sections before returning to the cover memo.

The screenshot shows a web application interface for an 'Application Cover Memo'. At the top, there are navigation links for 'Optional Cover Memo', 'Application Cover Memo', and 'Online Submission FAQ' and 'Online Submission Guide'. Below these are links for 'Quick View (HTML)', 'PDF', and 'Delete Submission'. The main content area contains a message from 'irbis.research.unc.edu' stating that all required sections of the application have not been completed. It explains that this could be due to new sections being added or changes made to the application. The message instructs the user to complete any sections in the navigation without a green check and to click and expand each section to view which individual items are not checked. A blue 'OK' button is positioned at the bottom right of the message box. At the bottom of the page, there are two buttons: 'Save and Stay' and 'Save and Continue'. A footer note at the bottom center reads: 'To navigate the Application, press any link in the Item List to your left.'