



# Management Of Incidental Findings At The EXPLORER Molecular Imaging Center

Department of Radiology

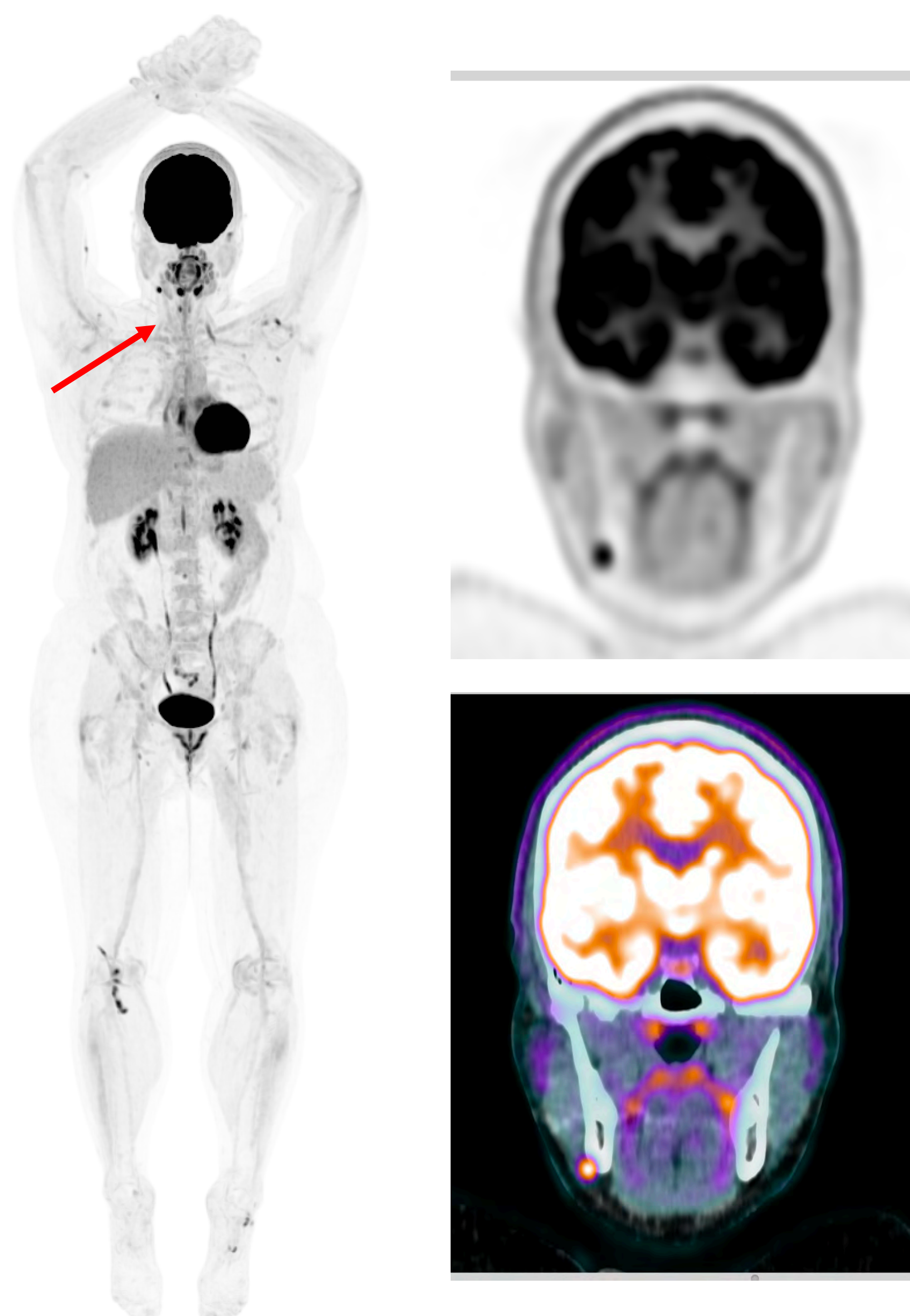
Ofilio Vigil, Lorenzo Nardo, John Tupin, Denise Caudle, Cameron Foster, Simon Cherry, Ramsey Badawi, and Dana Little

## Introduction

The world's first total-body PET scanner, EXPLORER, is operating at UC Davis Health (UCDH). It is utilized for research purposes and routine clinical PET/CT scanning.



Given EXPLORER's long axial field-of-view (194 cm) and ultrahigh physical sensitivity, allowing for simultaneous imaging of the entire body, the discovery of incidental findings (IFs) related to clinical problems in research volunteers is likely, potentially requiring follow-up procedures exposing them to additional risks.



Healthy research volunteer with an incidental finding at the right submandibular lymph node. Clinical correlation was recommended.

## Results

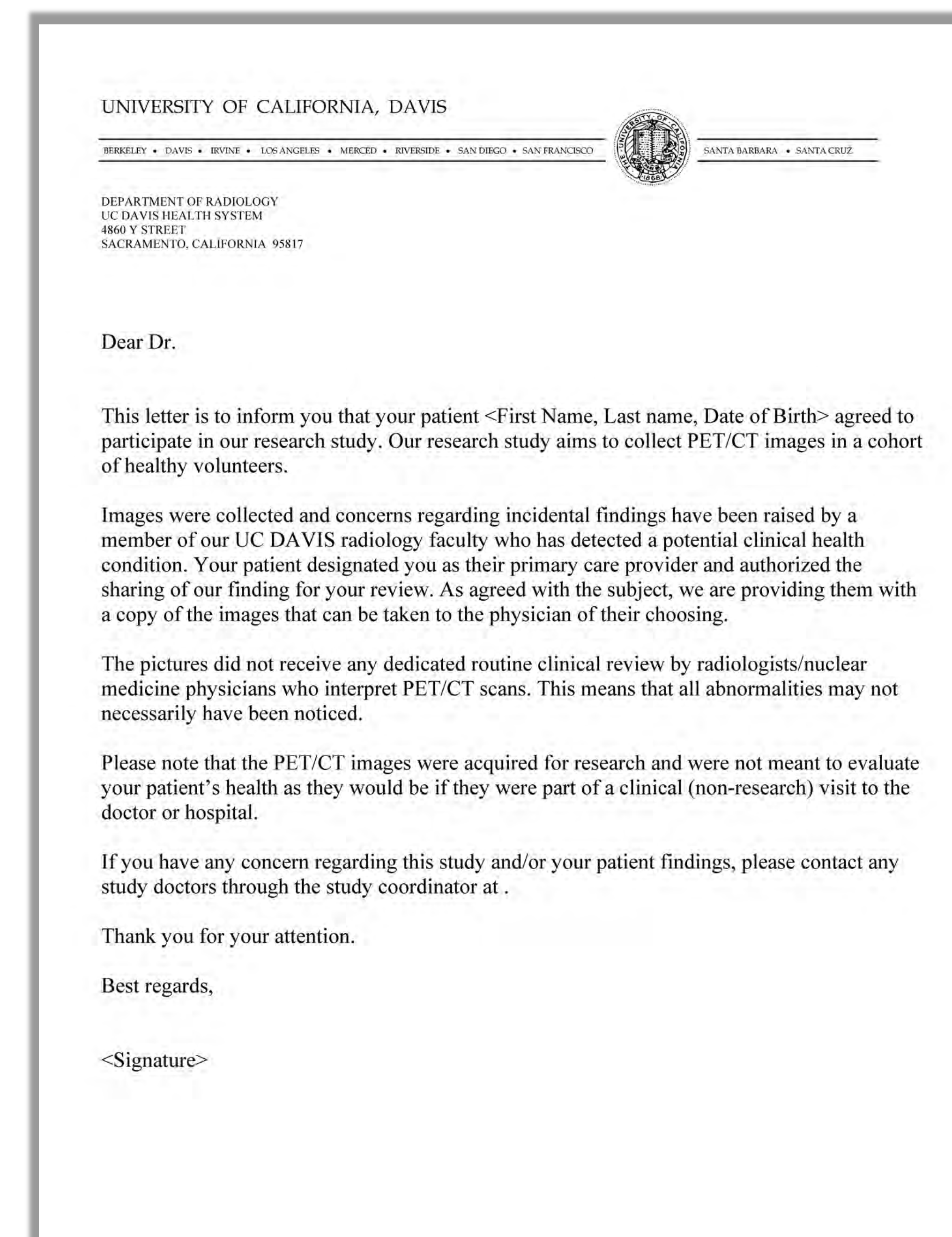
Lacking clear guidance in the context of this first-in-the-world scanner, we developed a plan to address IFs. We relay to participants, via the informed consent form (ICF), the possibility that findings related to a medical problem may be discovered.

"The PET/CT images created for this study are for research and are not meant to judge the level of your health, as they would be if they were part of your medical care. The images will not receive the usual clinical review by radiologists who interpret PET/CT scans. This means that some findings may be overlooked or misinterpreted. However, if a member of the study team, while reviewing your images, notices any findings they will share this with the Study Radiologist. If the Study Radiologist thinks a medical problem might be present, we will contact you within 8 weeks to discuss the possible medical problems or immediately if it appears urgent to the Study Radiologist. If you request it in writing, we can provide you with a copy of a section of your CT and PET images to take to a doctor you designate. We may not be able to share any images from the PET portion of your scan if they are difficult to interpret or if we are restricted by the sponsor of the study. We will send a letter to a doctor you designate letting them know that you are enrolled in this study and that it included getting a PET/CT scan for research. The letter will also state that the images did not receive the usual clinical review but that findings related to a possible medical problem were seen by a UC Davis radiologist. Your doctor can contact the Study Radiologist at any time to discuss your PET/CT scan."

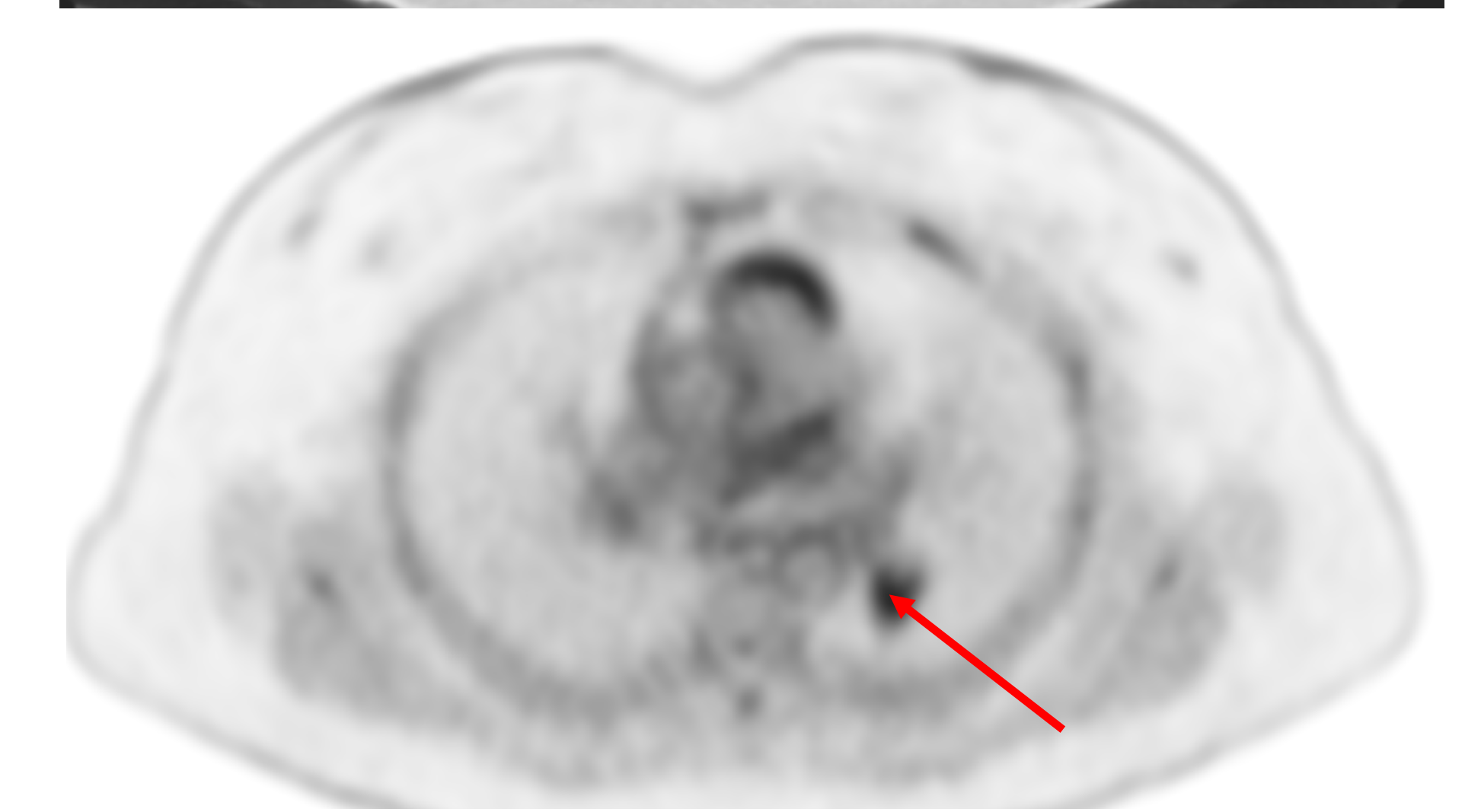
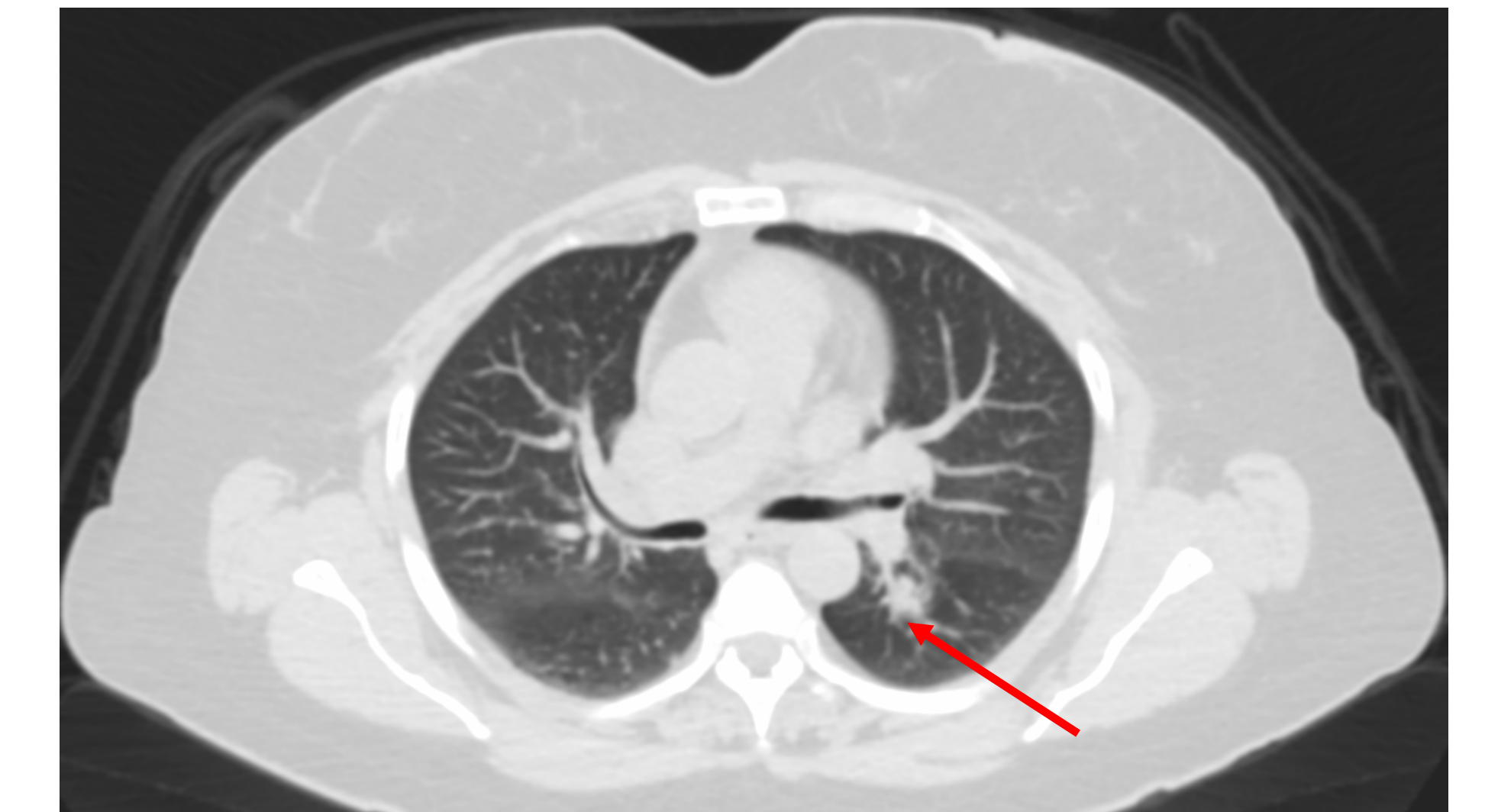
excerpt from ICF

When an IF is identified, our clinical research team works with the Study Radiologist and Principal Investigator to contact participants within 8 weeks of the scan to discuss it. However, if the IF requires urgent action, participants are contacted according to the UCDH Department of Radiology guidelines related to emergency findings.

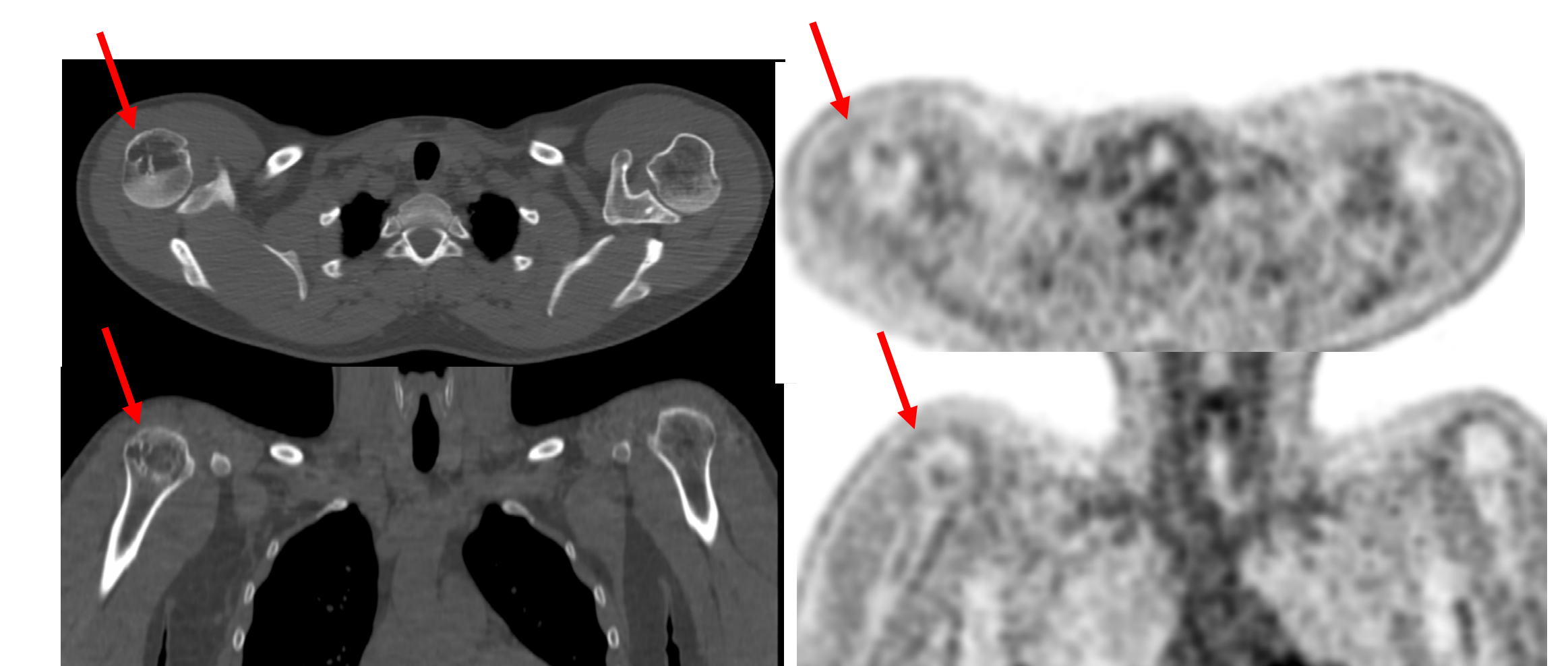
During consent, we ask all participants to provide contact information for their medical provider. If a participant requests, we provide them with a subset of their images to share with their medical provider. The research team will send a letter to their provider stating the purpose for the scan, the discovery of a potential problem, and the contact information for the Study Radiologist.



Sample of letter for medical provider reporting on IFs



Healthy volunteer with a left lower lobe pulmonary nodule. Further imaging was recommended



Healthy volunteer with a probably benign right humeral head lesion. Further imaging was recommended.

## Summary

This plan is described in all EXPLORER protocols with appropriate language included in the ICF. Our goal is to mitigate risks due to unnecessary follow-up while capturing benefits from important clinical findings obtained during cutting-edge research on EXPLORER.

## Acknowledgements

We thank all our research participants and members of NMROC for their review and discussion as we standardized IF language.