



TEMPLATE: HUMAN SUBJECT RESEARCH INITIAL REVIEW APPLICATION

This form is used for all researches submitted to the IRB. Please fill in this form and submit it along with:

- | | |
|---------------------------------------------|--------------------------|
| a. Research protocol submission checklist | b. Research protocol |
| c. Updated CV of all investigators | d. Data collection sheet |
| e. Proof of research ethics training course | f. GCP Checklist |

Protocol Title:	Diagnostic accuracy and complications of CT-guided core needle lung biopsy of solid and part-solid lesions in KFSH.		
Principal Investigator:	Name: Mahmoud Hussain Alabbad	KFSHD ID: 11863	
Contact information:	Mobile: 0562281333	Ext.:	Bleep:

Funding Source <i>(name of sponsoring Industry or Grant provider, N/A if none)</i>	N/A	Are you Applying for KASCT grant? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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Research staff (including principal investigator)			
Name/KFSHD ID	Role in the research ^(a)	Involved in consent?	Any conflict of interest ^b related to this research?
Dr Suha Albadr	1, 2, 7	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes_____
Dr Huda Ismail	1, 2	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes_____
Dr Mahmoud Alabbad	1, 2, 3	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes_____
Dr Lamma Algheryafi	1, 2, 3	<input type="checkbox"/>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes_____
		<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes_____
		<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes_____
		<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes_____
		<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes_____

^a **Role in Research** (please reflect the number below on the table above, investigator might take more than one role)

1. Protocol Development	3. Records / Lab Reports / ECGs Review, and Data Collection	5. Lab Report Review	7. Data Analysis (one person only)
2. Decide on Subject Eligibility	4. Study-Specific Physical Exams and Medical History	6. CRF Entries / Corrections	8. Other (please specify)

^b **Conflict of Interest (COI)** (please reflect the letter from below in the table above, more than one can apply)

An individual involved in research is automatically considered to have a COI when the individual, or the individual's immediate family (spouse and dependent children), have any of the following:

- a) Involvement in the design, conduct, or reporting of the research.



- b) Licensing, technology transfer, patents.
 - c) Financial interests of senior administrators, investments, ownership interest, stock options, relating to the research.
 - d) Gifts, compensation related to the research of any amount in the past year, or of any amount expected in the next year, including compensation for costs directly related to conducting the research.
 - e) Any other reason for which the individual believes that they cannot be independent in the case of a non-financial COI as there is no financial component to influence the research outcome, but the nature of the topic has the potential to bias judgment.
- If the a COI exists, please attach a COI management plan

Appendix A:

Is this a Single-Site or Multi-Site study?

(Multi-site research: The same research procedures are performed at multiple sites – for example, a multi-site clinical trial. In other words, there are multiple performance sites for a single study. There is often a lead institution that is the prime recipient of the funding for the overall study and that may be responsible for administrative oversight of the overall study. Typically, the prime recipient establishes sub-contracts with the performance sites. The lead institution may or may not also serve as one of the performance sites, and may or may not serve as a coordinating center.

Questions below are to help IRB assess how these responsibilities are carried out and ensure that all involved institutions are covered from a compliance point of view)

Single-Site

Multi-Site

If Multi-site: *(The institution of the lead Researcher of a multi-site study or the institution which provides study-wide services such as for data coordination.)*

Insert Coordinating Site Name	Insert Coordinating Site Type	Is that institution only involved as the coordinating center Yes/No	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email
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Performance sites: *(List of locations/sites at which human subjects research is performed by KFSHD personnel, but not by employees of the location.)*

Insert Performance Site Name	Insert Performance Site Type	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email
Insert Performance Site Name	Insert Performance Site Type	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email
Insert Performance Site Name	Insert Performance Site Type	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email
Insert Performance Site Name	Insert Performance Site Type	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email



Insert Performance Site Name	Insert Performance Site Type	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email		
Collaborative sites: (Institutions at which: (i) Human Subject research activities are carried out by the institutions employees. or (ii) Services provided by the institutions employees.)						
Insert Collaborative Site Name	Insert Collaborative Site Type	List Activities performed at this Site Type	IRB of Record*	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email
Insert Collaborative Site Name	Insert Collaborative Site Type	List Activities performed at this Site Type	IRB of Record*	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email
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Insert Collaborative Site Name	Insert Collaborative Site Type	List Activities performed at this Site Type	IRB of Record*	Insert Point Of Contact (POC)	Insert POC Phone	Insert POC Email

*IRB of Record: Which IRB is reviewing the research on behalf of the collaborators?

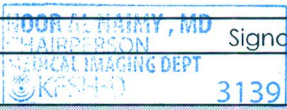

Appendix B: Product Use: Drug and Device						
<i>(List all Unapproved drugs being used; Approved drugs whose use is specified in the protocol; and/or Foods or dietary supplements being evaluated to diagnose, cure, treat, or mitigate a disease or condition)</i>						
Select Product Type	Provide Generic Name	Provide Brand Name	Check all what applies	SFDA Approvals	If used investigational, Check:	Describe storing, handling and administering Attach IB ^c
Drug/ Device			<input type="checkbox"/> Used as per standard of care Protocol <input type="checkbox"/> Used investigational	<ul style="list-style-type: none"> • Provide IND number • Provide communication or approvals 	<input type="checkbox"/> for a new indication, <input type="checkbox"/> for a new population, <input type="checkbox"/> in a new way (for example: different dosages, different route of administration)	
Drug/ Device			<input type="checkbox"/> Used as per standard of care Protocol <input type="checkbox"/> Used investigational	<ul style="list-style-type: none"> • Provide IND number • Provide communication or approvals 	<input type="checkbox"/> for a new indication, <input type="checkbox"/> for a new population, <input type="checkbox"/> in a new way (for example: different dosages, different route of administration)	
Drug/ Device			<input type="checkbox"/> Used as per standard of care Protocol <input type="checkbox"/> Used investigational	<ul style="list-style-type: none"> • Provide IND number • Provide communication or approvals 	<input type="checkbox"/> for a new indication, <input type="checkbox"/> for a new population, <input type="checkbox"/> in a new way (for example: different dosages, different route of administration)	



c for each approved drug include a copy of the package insert.

for each drug with an IND number, ensure that the application includes one of the following:

- Current investigator brochure
- Sponsor protocol with the IND number
- Communication from the sponsor with the IND number
- Communication from the SFDA with the IND number

Department Chairperson / Center Director Acknowledgement	
By signing below, I certify that I have reviewed this research project in its entirety and it is feasible within resources.	
 MOOR AL-HARIRY, MD CHAIRPERSON MEDICAL IMAGING DEPT KFSHD 3139	Signature
	Date
	May 19, 2022
Principal Investigator Acknowledgement	
By signing below, I have:	
<ul style="list-style-type: none">• Obtained all the necessary department approvals• Obtained the conflict of interest status ("yes" or "no") for each research staff• Obtained the agreement of each research staff to his/her role in the research• Read and understood the KFSHD INVESTIGATOR BOOKLET, and will conduct this Human Research in accordance with requirements in IT.• Ensured that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space	
Investigator signature	Date
	May 18, 2022