Template Language for your IRB Submissions when CMRR Resources are Utilized

When completing the IRB protocol template:

The following template language should be used in applicable sections of the protocol when CMRR Standard Forms & Procedures will be implemented as part of the research. The CMRR Standard Forms are IRB approved and managed under a CMRR Center Grant file (IRB# 1406M51205) as well as publically available on the CMRR website (CMRR Policies / Procedures).

To avoid review delays and to ensure consistent reporting of CMRR required activities, you are encouraged to use the following template language in applicable sections of the protocol:

When Recruiting Healthy Subjects using the CMRR volunteer pool (available *only* to Dept. of Radiology Faculty):

> *The research team will utilize the CMRR Center's volunteer pool for recruitment of healthy research volunteers in this protocol. The CMRR Center's volunteer pool is IRB approved under the CMRR Center Grant (HSC# 1406M51205) and information regarding volunteers is publically available on the CMRR website* (CMRR Policies / Procedures).

When using the CMRR Screening Form (required for all studies)

Language to use in ETHOS protocol (e.g. Section labeled "Procedures Involved"):

> *The research team will utilize the CMRR Center's screening tools and adhere to the screening SOP during enrollment of all research participants in this protocol. The CMRR Center's screening tools and SOP are IRB approved under the CMRR Center Grant (HSC# 1406M51205) and information regarding screening procedures is publically available on the CMRR website (CMRR Policies / Procedures).*

Subject information Form (required for studies on systems above 3T)

Language to use in ETHOS protocol (e.g. Section labeled "Provisions to Monitor…") when applicable:

> *The research team will utilize the CMRR Center's Subject Information Form and adhere to the SOP during enrollment of all research participants in this protocol. The CMRR Center's Subject Information Form and SOP are IRB approved under the CMRR Center Grant (HSC# 1406M51205) and information regarding these procedures is publically available on the CMRR website* (CMRR Policies / Procedures).

Exit Questionnaire (required for studies at 10.5T)

Language to use in ETHOS protocol (e.g. Section labeled "Provisions to Monitor…") when applicable:

> *The research team will utilize the CMRR Center's Exit Questionnaire and adhere to the SOP during completion of all research participants' MRI scanning in this protocol. The CMRR Center's Subject Exit Questionnaire and SOP are IRB approved under the CMRR Center Grant (HSC# 1406M51205) and information regarding these procedures is publically available on the CMRR website* (CMRR Policies / Procedures).

Consent Form | Language and Common Text

Consent forms must include specific language regarding the research MRI(s). The research team is responsible for reviewing the CMRR's SOP's and consent form template for specific language requirements (Consent Form Template). Examples of required language include, but are not limited to, the following: Risks of MRI (standardized risk language), procedures associated with identification of incidental findings, significant new information (when required), etc.

When completing the ETHOS application:

Question 1 – Study Scope

1. * What type of research is being conducted?
Biomedical / clinical

- Select "Biomedical/Clinical"
- Studies utilizing CMRR resources (i.e. medical devices) are always considered "Biomedical/clinical".

Question 7 – Use of medical devices

On the Study Scope page select "yes" to Question 7 "Use of Medical Devices", if you are using any MR scanner at CMRR (3T-A,B,C, 7T/AS, 7T/Terra, or 10.5T) or the 3T-D scanner at MiDB.

- All studies using the CMRR magnets need to fill the device page out whether they are evaluating the safety or effectiveness of the device or not. **PLEASE NOTE: This is a change to how we have been handling this previously.**

7. * Use of medical devices

Does the protocol:

- Evaluate the safety or effectiveness of a device?
- Use a humanitarian use device (HUD)?

● Yes ○ No Clear

>> Click "continue" to the next page. This page gathers much more information about the device(s)<<

Devices

1. * **Select each device the study will use to evaluate for safety or effectiveness, or as a HDE:**

Add

Device	Humanitarian Use Device	Added Manually?	Atachment Name
There are no items to display			

2. * **Which description below best characterizes your study? Click the help button for definitions.**

- ○ Early Feasibility
- ○ Feasibility
- ○ Pivotal
- ○ Post-approval
- ○ Expanded access

Clear

3. * **Select the option below that best describes your device:**

- ○ IDE
- ○ HDE
- ○ Claim of abbreviated IDE (nonsignificant risk device)
- ○ Exempt from IDE requirements

Clear

4. **For all applicable devices, provide IDE numbers or indicate NSR:**

Add

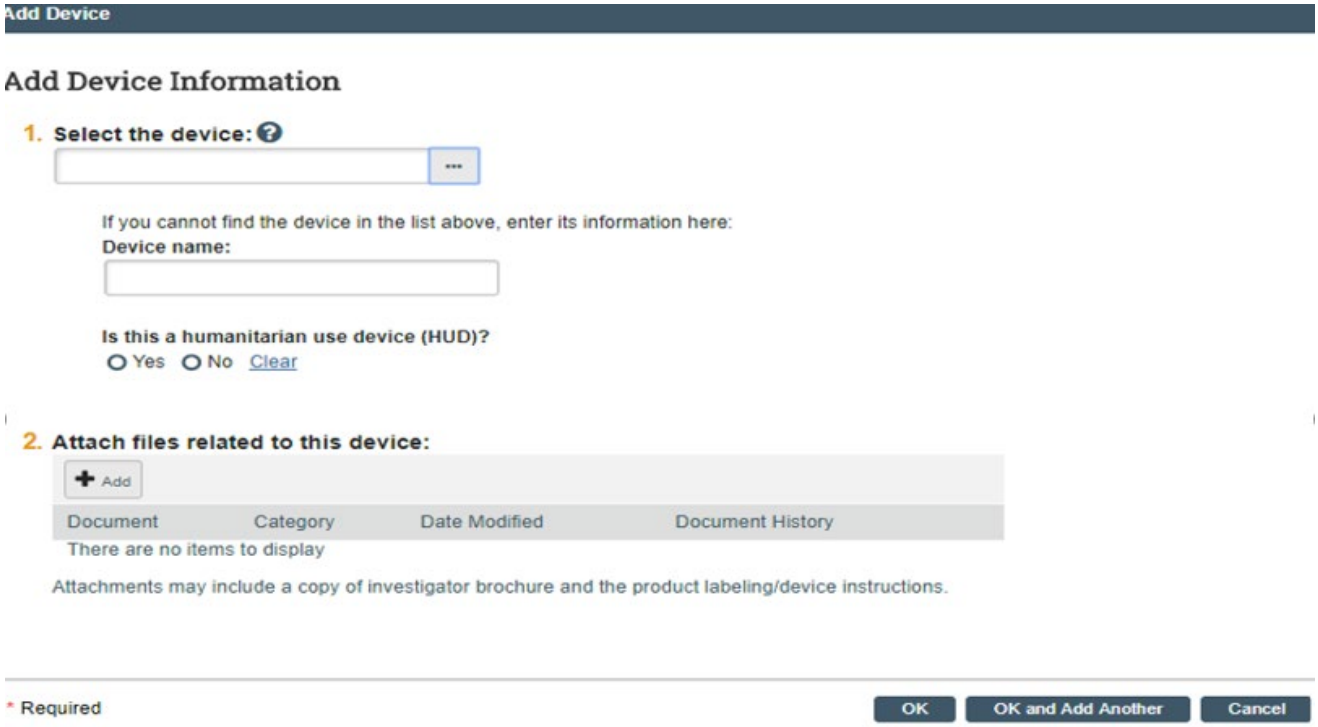
IDE Number/NSR	IDE Holder	Other Holder
There are no items to display		

5. **Attach files: (Device information that was not previously attached)**

Add

Document	Category	Date Modified	Document History
There are no items to display			

How to add devices to a study:



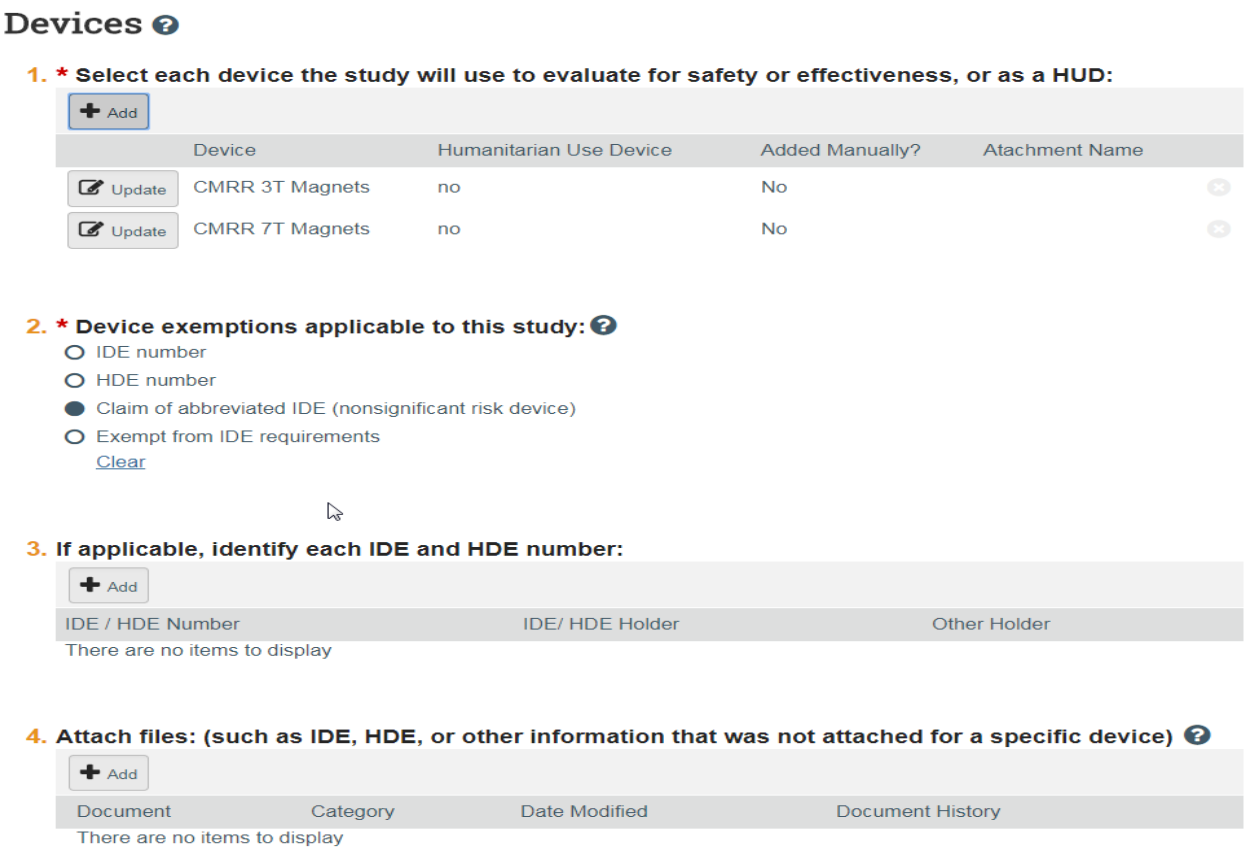
How to Add Device Information Pop-up:

Enter CMRR in the box next to "Device Name" to see available selections.
Note that CMRR MR Scanners are not Humanitarian Use Devices (HUD's)

After making your selection and clicking "OK" you will return to the Device Information pop up.

There is no need to attach additional documents related to the CMRR device(s) so long as the research does not include any revision or modification to the existing CMRR devices. Note, information regarding these specific CMRR devices is centrally managed under the CMRR Center Grant file (IRB# 1406M51205) and accessible to IRB reviewers.

Devices Page



Question #2 Device exemptions applicable to this study:

Device Exemptions:

- 3T and 7T-Terra – Exempt from IDE Requirements if using FDA approved coils (please contact CMRR if you have any questions)
- 7T/AS – Claim of abbreviated IDE (NonSignificant Risk devices)
- 10.5T – IDE number (Contact CMRR for details)

Question#3 & #4 IDE and HDE number:

Only necessary for 10.5T studies.

>> Complete the remainder of the ETHOS application with your project-specific information <<