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## STANDARD OPERATING PROCEDURE

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### News Releases or Recruitment Materials Regarding Research

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#### 1.0 PURPOSE

This procedure establishes the process to:

- 1.1 Identify research-related news releases and recruitment materials that require IRB review prior to release to the public by The Christ Hospital Health Network (TCHHN) Public Relations Department. (Ref. [21 CFR 56.111\(a\)\(3\)](#), [45 CFR 46.111\(a\)\(3\)](#), [21 CFR 56.111\(b\)](#), [45 CFR 46.116\(a\)\(2\)](#))
- 1.2 Balance the public's interest in being informed of major news items through the news media, while remaining, at all times, fully compliant with federal Privacy Rules, specifically Sections [45 CFR 164.510](#), [45 CFR 164.514](#), and [21 CFR 312.7\(a\)](#), governing the Use and Disclosure of Individual PHI.

#### 2.0 POLICY

TCHHN, including The Christ Hospital Institutional Review Board (TCH IRB), recognizes the public's interest in being informed of major news items through the news media. At the same time, TCHHN's first obligation is to protect the privacy and confidentiality and their Personal Health Information (PHI) of patients, ensure equitable selection of participants in research, as well as prevent any undue influence and/or coercion.

TCHHN Public Relations (PR) and Marketing Department has primary responsibility for release of patient information and clinical research information to the news media. (Ref. TCHHN Administrative Policies: [4.30.108](#) and [4.30.110](#).)

The IRB must review and approve all media or publications used to recruit subjects for research (e.g., advertising through radio, TV, newspaper) conducted at The Christ Hospital as outlined in [SOP 2.10 - Recruitment of Subjects in Research](#).

#### 3.0 RESPONSIBILITY & PROCEDURE

##### 3.1 TCHHN Public Relations and Marketing Department

TCHHN Public Relations Department holds the primary responsibility for release of Individual information and clinical research information to the news media

including when such information may be released to the media and consistent with guidelines of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. When members of the news media contact physicians and/or others involved in clinical research projects at TCH, media members must be referred to the Public Relations and Marketing Department at 513-585-1452. Any calls made to members of the news media must be made or cleared through Public Relations, as addressed in TCH Administrative Policy [4.30.108](#).

## 3.2 IRB

### 3.2.1 News Releases

The IRB shall confirm the accuracy of all information regarding research protocols for use in press releases regarding research.

### 3.2.2 Materials For Recruitment of Research Participants:

All publications or media used to recruit subjects for research (i.e., radio ads, TV ads, newspaper ads, etc.) conducted at The Christ Hospital must be reviewed and approved by the IRB as outlined in [SOP 2.10 - Recruitment of Subjects in Research](#). Advertisements that are easily comparable to an approved informed consent document may undergo review and approval using the expedited review procedure. For more information regarding recruitment of research subjects, refer to [IRB Reference Manual 5.0 Recruitment](#).

## 4.0 REFERENCES

- 4.1 The Christ Hospital IRB Standard Operating Procedure: [SOP 2.10 - Recruitment of Subjects in Research](#)
- 4.2 The Christ Hospital IRB Reference Manual: [RM 5.0 Recruitment](#)
- 4.3 The Christ Hospital Administrative Policies
  - 4.3.1 [4.30.108](#) - Release of PHI to the News Media
  - 4.3.2 [4.30.110](#) - Release of Patient and Clinical Research Information to the News Media
- 4.4 The U.S. Department of Health and Human Services Policies
  - 4.4.1 [45 CFR 164.510](#)
  - 4.4.2 [45 CFR 164.514](#)
  - 4.4.3 [45 CFR 46.111\(a\)\(3\)](#)
  - 4.4.4 [45 CFR 46.116\(a\)\(2\)](#)
- 4.5 U.S. Food and Drug Administration (FDA) Policy
  - 4.5.1 [21 CFR 312.7\(a\)](#)
  - 4.5.2 [21 CFR 56.111\(a\)\(3\)](#)
  - 4.5.3 [21 CFR 56.111\(b\)](#)