**All IN for Health iConnect IRB Language Guide**

**The following information is based on the current IU Human Subjects Office (HSO) forms and related to using Indiana CTSI iConnect, All IN for Health, study listing and volunteer registry as a recruitment tool. This information is to help you supplement your recruitment sections of your KC-IRB submission. You may need to alter this depending on which capabilities you are using in the system. In addition, other investigational review boards may ask for additional information. *Please Note: Not all information in this guide may apply to you. Please choose the sections that correspond with your needs. We encourage you to check with your institution/IRB of record if you have specific questions regarding requirements for your IRB submission.* For questions, please contact the Indiana CTSI Admin Team at** [**inhealth@iu.edu**](mailto:inhealth@iu.edu)

**\*\*Highlighted items are placeholders for the information you may include with your IRB submission.**

**The following is a list of items that you may customize and include with your application:**

* **Template A: iConnect Study Listing page (***you will take a screenshot of your finalized listing – see examples***)**
* **Template B: Volunteer Outreach Email Message Template**
* **Template C: Study Team Reply Email Message Template**
* **\*\*OPTIONAL Template D: Volunteer Registry Email Letter** (*created for you by CTSI Admin – to be used for studies in which CTSI has determined this service would be optimal for communication purposes for volunteers and CTSI will be sending emails out to registrants on behalf of your study team***)**

**KC Protocols – Section “Eligibility and Recruitment”**

**Q. #0307: Describe your recruitment process…**

Our study will be listed on the Indiana CTSI study listing called the All IN for Health *TrialX iConnect.* iConnect is a HIPAA-compliant and secure public facing research recruitment platform provided by the Indiana Clinical and Translational Sciences Institute (Indiana University) consisting of a study trial listing and volunteer registry. This system is licensed by Indiana University from TrialX and is monitored by the Indiana University Information Technology Services (UITS) and University Information Security Office (ISO).  Study Teams have access to their study listings and participant referrals based on a secure login.  There is a small Administrative Team within the Indiana CTSI that manages the iConnect platform and has access to all study information, referrals, and registry volunteers. This online platform provides researchers with the ability to create a public facing webpage that can contain a brief prescreener and the ability for the public to refer themselves to the trial: (<https://research.indianactsi.org>). The study listing information can be modified based on the study and targeted population and provides a direct, easily managed system to enhance communication with the public. Study teams can also use this webpage as the landing or referral page for any marketing materials that are being used (either by listing the hyperlink or creating a scannable QR code). We have included a screenshot of our study listing for your review and approval. Please see attachment titled *(insert Template A file name of “iConnect study listing page” screenshot file here).*

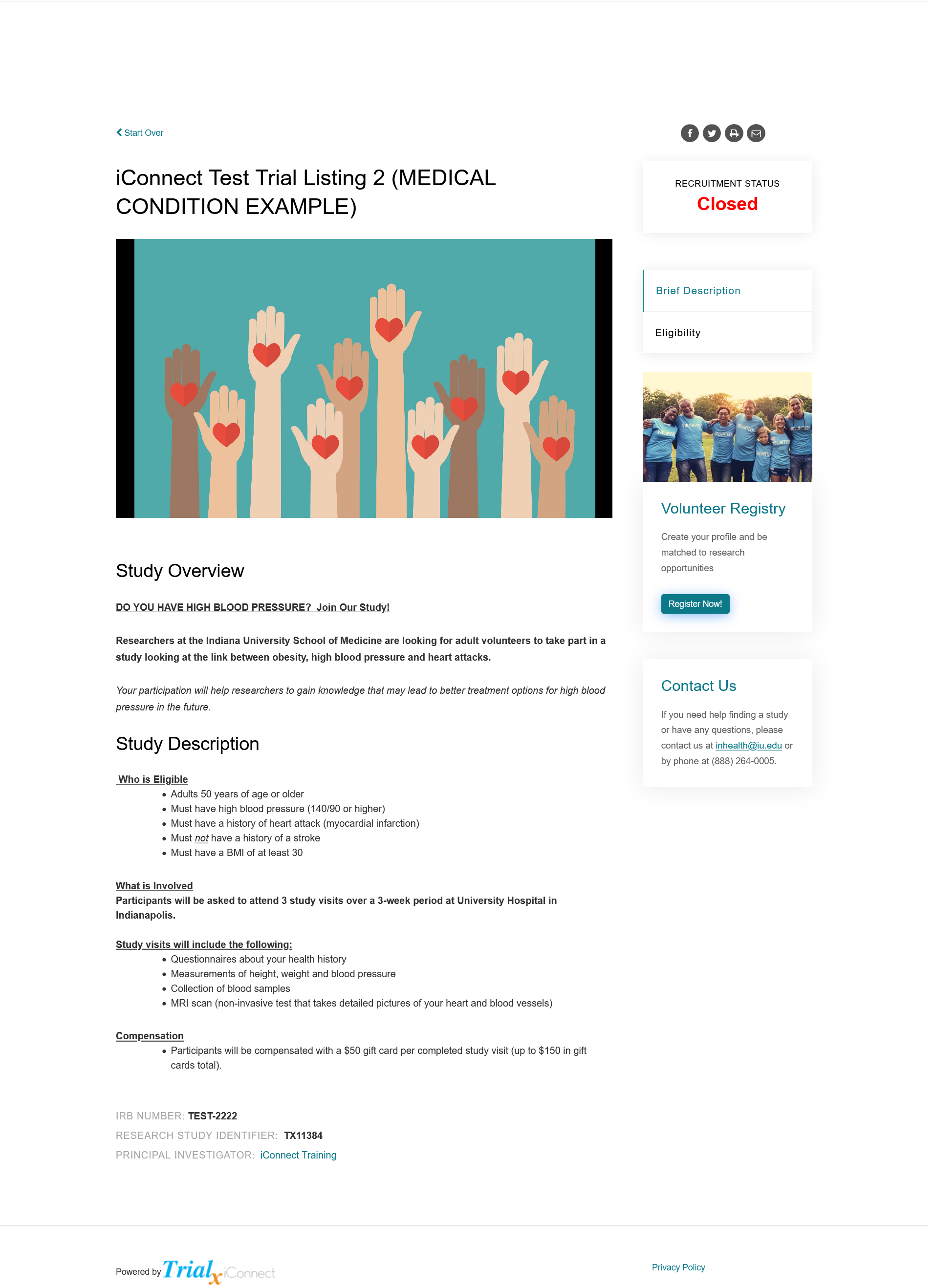
The study listings are open to the public and any persons who visit our study page may submit their contact information to us through the listing. We can access that information by logging in to our iConnect dashboard. We may respond to and contact interested volunteers directly through the platform or by university phone or email. We will use the following guide for any email responses for phone conversations with the volunteers. For our standard messaging, please see attached [insert *Template C file name of “Study Team Reply Email Message Template”).*

In addition to the study listing(s), potential participants will be identified from the Indiana CTSI All IN for Health voluntary registry IU IRB Protocol Number 1105005444. This registry was created so that interested individuals could create a volunteer profile to receive information about ongoing studies. Persons in this registry have provided their self-reported health information for the purposes of being matched to appropriate research studies. The registry volunteers have signed an electronic consent/authorization so that their information can be used and they can be contacted for this reason.

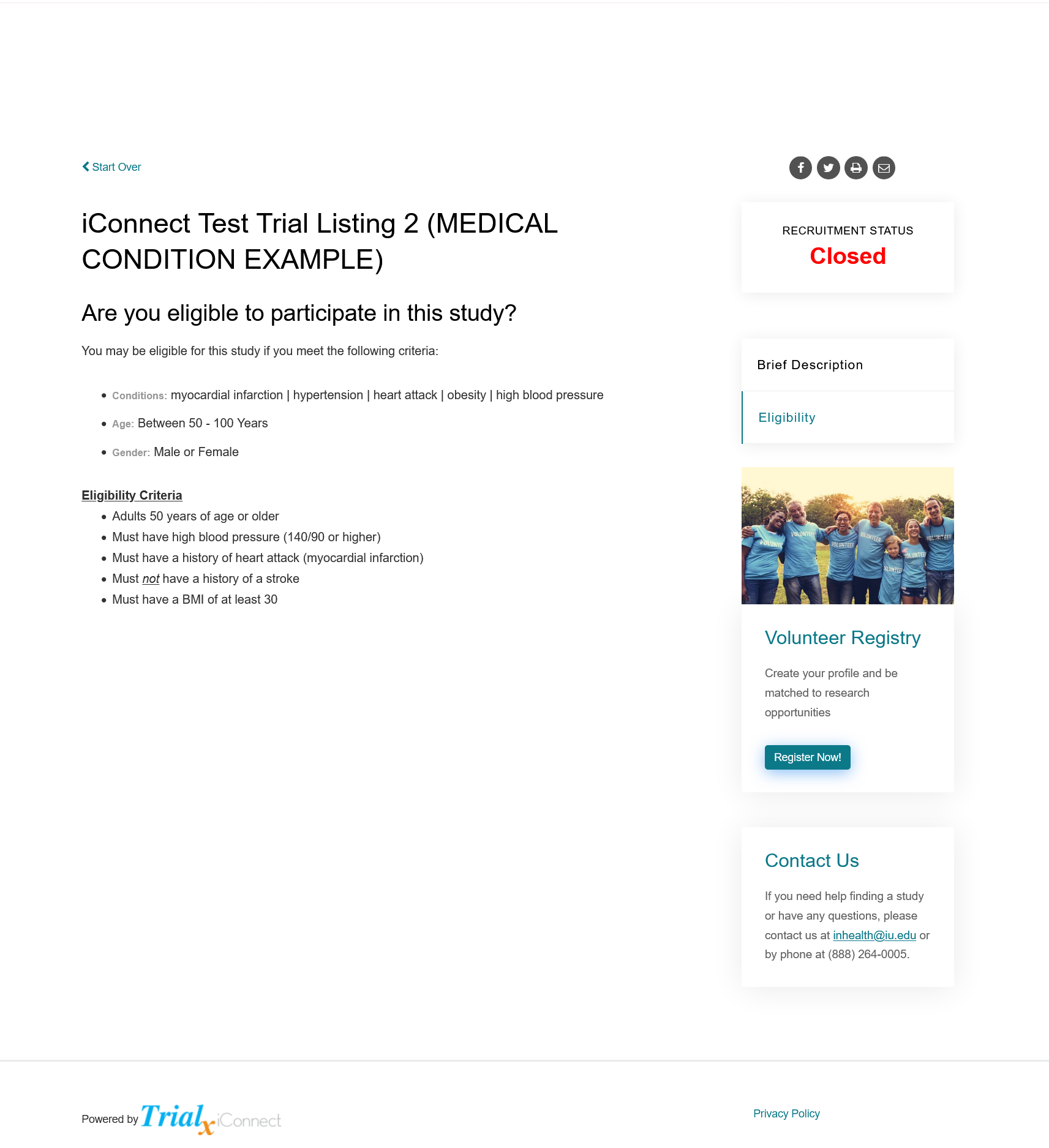
We can also match participants in the registry and are able to send out a message to them through the system in a de-identified manner. We may use the search and filter tool in the system to identify a group of volunteers who match our study criteria based upon the information that the volunteers have included in their profiles. We may then send an outreach message to those de-identified matched volunteers through the online system. If we send an outreach message to matched volunteers, we will use standard messaging (please see attached *[insert Template B file name of “Volunteer Outreach Email Message Template.”]* Matched volunteers who receive our outreach message and indicate they are interested and agree to be contacted specifically for this study will approve for their contact information to be accessible by us through the iConnect portal. If we contact those interested matched volunteers by email or phone, we will use the language from Template C [file name of “Study Team Reply Email Message Template”] for any email responses for phone conversations with the matched volunteers.

*OPTIONAL TEXT (TEMPLATE D):* Using the study criteria, the system allows the Indiana CTSI and/or the study team to identify a group of potentially eligible participants. Study teams may request the Indiana CTSI recruitment team to send an email to those volunteer registry participants explaining the study and asking them to participate in the study. A copy of the email letter(s) is attached *(insert Template D file name of “Volunteer Registry Email Letter” file(s))*.

**Template A: iConnect Study Listing Page Example (Page 1)**



**Template A: iConnect Study Listing Page Example (Page 2)**



**Template B: Volunteer Outreach Email Message Template**

(To use when contacting registry volunteers via email outreach message through the iConnect system)

\*\*Items in **blue** indicate that they are pre-populated in the message

\*\*Items in red need to be added to the message before sending

*Please contact CTSI Admin if you would like us to review your message and offer feedback prior to sending,*

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**Message Template**

Study Title **Title**

From  **Name**

To **Volunteer**

Subject: ADD TEXT HERE (short tag line starting with *Research Study Looking For*… (\*\*we recommend including age and/or population (i.e. children, adults, seniors) with condition) - SEE EXAMPLE BELOW

Thank you for being an All IN for Health Research Volunteer! We have found the following study that you may quality for:

**STUDY TITLE HYPERLINKED TO LISTING**

OPTIONAL TEXT: Our study is looking for people who [target condition/population]. If eligible, you may be reimbursed up to [amount/type such as gift card].

If you are interested, click on “I’m Interested” to learn more about the study and contact us through the study listing form. If you are not interested in learning more or participating, click “I’m Not Interested.”

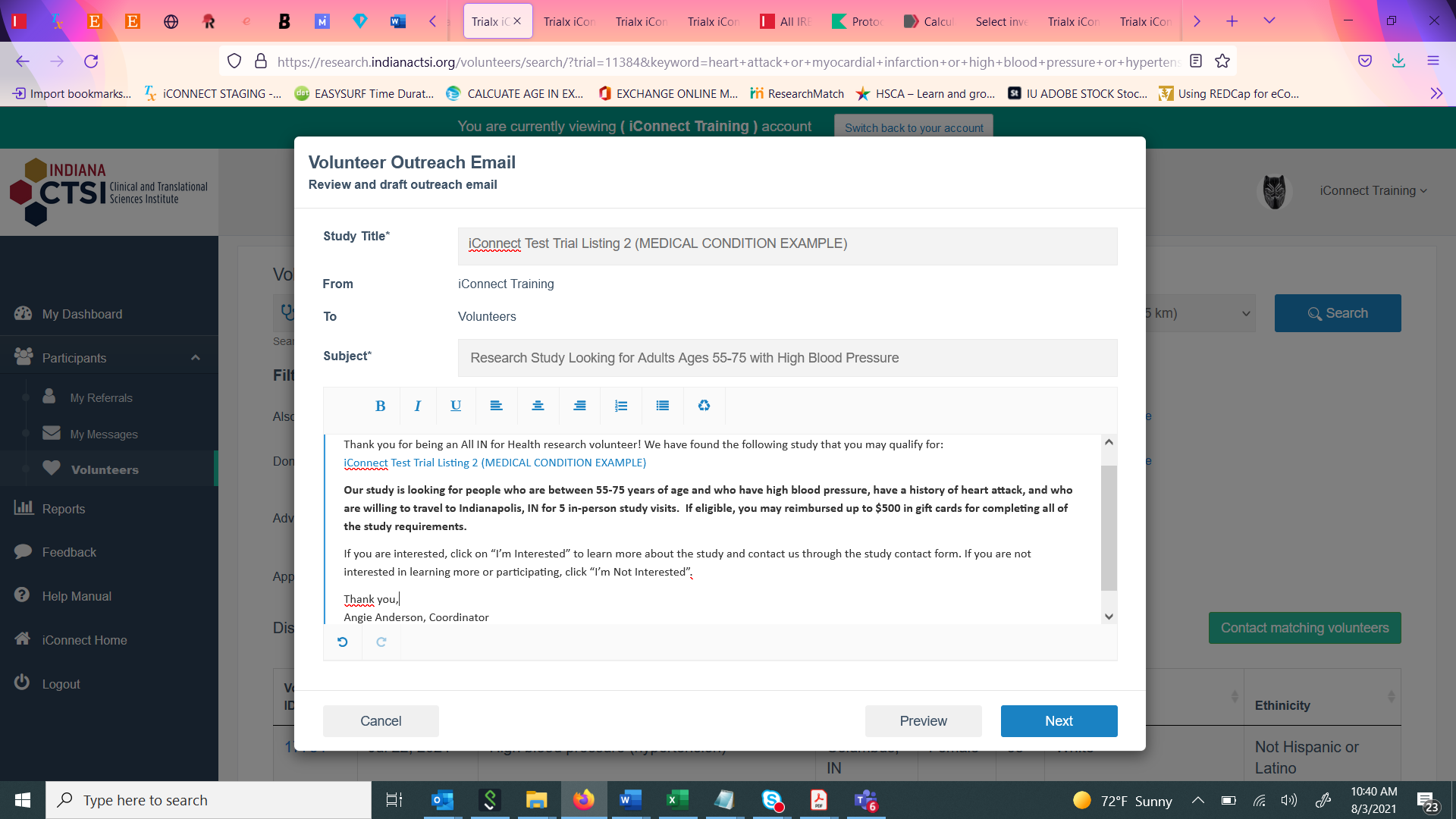
**I’m Interested**

**I’m Not Interested**

Thank you,

Name and Title

**Volunteer Outreach Message Example**



**Template C: Study Team Reply Email Message Template**

(To use when responding to volunteer replies/inquiries via email messages)

*\*\*Items in red need to be added to message*

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**Message Template**

Hi [participant name],

We are reaching out to you because we received your information indicating that you may be interested in participating in our study.

Our research study called [short or user-friendly title]is looking for [criteria, condition, study population].

The goal of this study is to [short statement of study focus or purpose].

**When is a good time for us to reach out to you about this study? Please email us back and let us know your availability.**

Thank you for your interest in our study!

[Name and Title or Study Team Name and Contact Information]

**\*\*OPTIONAL Template D: Volunteer Registry Email Letter***(created for you by CTSI Admin – to be used for studies in which CTSI has determined this service would be optimal for communication purposes for volunteers and CTSI will be sending emails out to registrants on behalf of your study team****)***

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Dear «CONTACT\_FIRST\_NAME»,

Thank you for your participation in [All IN for Health](http://www.allin4health.info)’s Volunteer Registry!

**[Opening Subject/Tag Line]**

**You may be eligible for this study if you:**

* [Eligibility criteria]

**For this study, you will be asked to [visits involved, number, location]**

**If you are eligible and choose to participate, you will be asked to do the following:**

* [Tasks involved (what will participants be asked to do)]

**Your study participation will last [amount of time] and** **you will receive [compensation type and amount(s)] for completing all of the study requirements.**

**Please reach out to the study team directly by contacting [study contact] at [email] or [phone number] if you are interested in taking part in this study.** (IRB Number: )

Thank you for your time and continued interest and support of our research.

Warm regards,

The All IN for Health Team

[www.allin4health.info](http://www.allin4health.info)

inhealth@iu.edu

1-888-264-0005



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